Human Research Ethics Committee Conference

# 6th Australian and New Zealand HREC Conference 25 – 27 November 2025

*V3 25 November 2025*
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# Foreword

Dear friends, colleagues and attendees

The 6th Australian & New Zealand HREC Conference is upon us, and this year there are a few changes. It is the first effort to establish a joint Australia and New Zealand HREC Conference. This presumptive association recognises that we have similar ethics review systems but also a shared context from which each can learn. We are delighted to have, as part of our organising committee, Dr Lindsey Te Ata o Tū McDonald, and Associate Professor Josephine Johnston, 2 key figures in ethics review in New Zealand. We are also delighted that the conference is being widely promoted in New Zealand, so we should have significant representation from across Aotearoa.

The second significant change is that due to the increasing popularity of the conference, we have had to have a pre-conference day, where ethics coordinators and paediatric research will have separate sessions. Unlike last year, where we were able to include all abstracts submitted on the topic of consumer and community engagement in research in the same session, this year we weren't able to include all abstracts in this session. We took the decision that we will endeavour to offer a half-day workshop on the topic of consumer and community engagement in research around March 2026.

The conference continues to be free of charge. At a time where conference attendance is precluded to many by cost, the HREC Conference continues to support HREC members, coordinators, researchers and the community to reach a shared understanding and to engender quality in ethics applications and their review, leading to better research outcomes.

With a view to improving quality, we have endeavoured this year to make sure that each session is relatable and that everyone who attends will be able to take away key points and learnings that can be operationalised. This can be a tricky task, but with the assistance of a committed Organising Committee, we feel we have again put together a program that will achieve this aim.

As our keynote speakers, we are delighted to have the wisdom of Aaron Zamykal talking about AI in health, Professor Seema Shah talking about the ethics of intentional infection research, and A/Professor Stephen Adelstein, Chair of the Australian Health Ethics Committee.

In addition to the esteemed keynote speakers, the program also comprises a variety of overseas speakers talking about clinical trials (Dr Francois Bompart, France), community-based participatory research (Associate Professor Adam Becker, US), artificial intelligence and ethics (Dr Joel Seah, Singapore), the Canadian CanReview Project (Susan Marlin), the ethics of advising (Dr Monique Jonas, NZ) and data management (Emma McDonald, NZ) as well as many highly qualified and fascinating Australian-based speakers.

I am again grateful to the members of the Organising Committee, listed in this booklet, who have provided invaluable input into the program and whom you will see when they chair sessions. I am also grateful to the supporters of the conference and notably Health Translation Queensland, whose conference coordination and administrative support makes this a seamless conference experience.

We hope that you can find many interesting talks that will help you on your ethics journey whether it be understanding the complex milieu of considerations or simply listening to certain topics that are of interest.

Best wishes for the conference

**Adjunct Professor Gordon McGurk PhD, JD, FGIA, GradDipLP, GAICD**
Convenor HREC Conference
Southern Cross University
Director, OmniAdvisory Consulting

# Organising Committee

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|---|---|
| Adjunct Professor Gordon McGurk | Southern Cross University |
| Dr Hudson Birden | Townsville Hospital and Health Service |
| Dr Janelle Bowden | Accessor CR |
| Associate Professor Mandy Downing | Curtin University |
| Dr Lisa Eckstein | CT:IQ |
| Sophie Gatenby | The Royal Children's Hospital Melbourne |
| Associate Professor Josephine Johnston | University of Otago, NZ |
| Professor Anthony Leicht | James Cook University |
| Associate Professor Robert Stanton | Central Queensland University |
| Dr Lindsey Te Ata o Tū McDonald | Canterbury University, NZ |
| Professor Nikolajs Zeps | Monash University |

All times in AEST (QLD)

**11:00 – 13:00** **National Ethics and Governance Coordinators Community of Practice**
**Led by Sophie Gatenby and Sara Hubbard**

*National Mutual Acceptance Scheme*
**James Cokayne, August Marchesi, David O'Halloran**
NSW Ministry of Health, Canberra Health Services, Department of Health Tasmania

**14:00 – 16:00** **Paediatric Research**
**Led by Sophie Gatenby**

*Research involving children and young people presents unique ethical, regulatory and operational challengers. This workshop explores how to elevate practice in paediatric research governance by:*

- *unpacking the concepts of consent and assent in young participants*
- *exploring the implications of the newly revised section 4.3 of the National Statement on Ethical Conduct in Human Research*
- *brining a practical focus to how ethics applications, review and monitoring can reflect best practice*
- *enabling dialogue between HRECs nationally.*

**Speakers:**
*Consent in paediatric research – foundational issues, regulatory landscape and practice implications*
**Adjunct Professor Gorden Mc Gurk**
Southern Cross University

*Assent – what it means, how we apply it and can we do so consistently?*
**Dr Scott Fisher**
Research Ethics & Governance Child and Adolescent Health Service, WA

*Reflective journey through the chapter 4.3 and operationalising updates – first-hand reflections and implementation ideas*
**Sophie Gatenby**
RCH Melbourne

**Panel discussion:**
Following the presentations, an interactive panel including representatives from paediatric HRECs will respond to queries about operationalising the National Statement chapter 4.3 and opportunities to standardise paediatric HREC review.

For further information, please contact Sophie.gatenby@rch.org.au or sara.hubbard@health.qld.gov.au.

# Day 1 – Tuesday 25 November 2025

All times in AEST (QLD)

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| **10:00 – 10:30** | **Conference opening** |
| 10:00 – 10:10 | **Welcome**<br>**Adjunct Professor Gordon McGurk**<br>Southern Cross University |
| 10:10 – 10:20 | **Acknowledgement of Country**<br>**Greg Pratt**<br>Central Queensland University \| QAIHC |
| 10:20 – 10:30 | **Opening remarks**<br>**Associate Professor Stephen Adelstein**<br>Royal Prince Alfred Hospital \| NSW Health Pathology \| RPA Institute for Academic Medicine \| University of Sydney<br>**Dr Elizabeth Fenton**<br>University of Otago |
| **10:30 – 11:15** | **Plenary**<br>**Chairperson: Adjunct Professor Gordon McGurk** |
| | *Agentic AI – Its impact on health & ethics*<br>**Aaron Zamykal**<br>Actualisation |
| **11:15 – 12:30** | **Technology & AI**<br>**Chairperson: Associate Prof Tam Nguyen** |
| 11:15 – 11:35 | *Would we want generative artificial intelligence in institutional review boards?*<br>**Joel Seah**<br>NUS Singapore |
| 11:35 – 11:55 | *AI = All In? How can HRECs address the 'new research normal'?*<br>**Professor Michael Martin**<br>Australian National University, Australian Health Ethics Committee |
| 11:55 – 12:15 | *Human-in-the-loop: balancing innovation and accountability in law enforcement use of AI*<br>**Andrew Chen**<br>New Zealand Police |
| 12:15 – 12:30 | *Thoughts from the chair and discussion*<br>**Associate Prof Tam Nguyen**<br>Monash Health |
| **12:30 – 12:40** | **Break** |
| **12:40 – 13:55** | **Consent & consent forms**<br>**Chairperson: Adjunct Professor Gordon McGurk** |
| 12:40 – 13:00 | *Social media and ethics review: identifying potential scandals & protecting participants*<br>**Professor Paula Swatman**<br>Bellberry |
| 13:00 – 13:15 | *Can 16- and 17-year-olds give consent to participate in research without parental consent?* |

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| | **Professor Richard Gray**<br>La Trobe University |
| 13:15 – 13:35 | *The InFormed Project*<br>**Dr Lisa Eckstein & James Cockayne**<br>CT:IQ & NSW Ministry of Health |
| 13:35 – 13:55 | *What can HRECs learn from the ShED project: waivers, secondary data usage, exemptions and HREC quality assurance*<br>**Adjunct Professor Gordon McGurk**<br>Southern Cross University |
| **13:55 – 14:05** | **Break** |
| **14:05 – 15:30** | **Data management**<br>**Chair: Adjunct Professor Gordon McGurk** |
| 14:05 – 14:25 | *Using personal information in research: some recent legal cases*<br>**Sonja Read**<br>MinterEllison |
| 14:25 – 14:45 | *Creepy or just complex? Making ethical decisions in a messy world*<br>**Emma MacDonald**<br>Stats NZ |
| 14:45 – 15:00 | *New horizons: a draft governance framework for synthetic health data in Australia*<br>**Keren Pointon, Carly Olsen & Dr Amir Marashi**<br>Digital Health CRC |
| 15:00 – 15:15 | *Embedding Indigenous Data Sovereignty principles across organisational research practice: practical strategies for ethical governance and community benefit*<br>**Nicole Hewlett & Imelda Ryan**<br>Mater Research |
| 15:15 – 15:30 | *But who owns the data? A case study from the evolving digital health landscape*<br>**Liesel Higgins**<br>CSIRO |
| **15:30 – 15:40** | **Break** |
| **15:40 – 16:55** | **Operationalisation & quality assurance**<br>**Chair: Professor Nikolajs Zeps** |
| 15:40 – 16:00 | *Brief overview of changes to National Statement*<br>**Jeremy Kenner**<br>NHMRC |
| 16:00 – 16:20 | *Ethics of advising*<br>**Associate Professor Monique Jonas**<br>University of Auckland |
| 16:20 – 16:35 | *Revisiting the 2024 Declaration of Helsinki: critiques and implications for human research ethics review*<br>**Dr Ehsan Shamsi Gooshki**<br>Monash Bioethics Centre |
| 16:35 – 16:55 | *Crossing the line: the contested space between quality and research*<br>**Rachel Kerr**<br>Monash University |
| **16:55** | **Close** |

All times in AEST (QLD)

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| **08:30 – 09:15** | **Plenary**<br>**Chairperson: Adjunct Professor Gordon McGurk** |
| | *The ethics of intentional infection research*<br>**Professor Seema Shah**<br>Lurie Children's Hospital, Chicago, USA |
| **9:15 – 9:55** | **Clinical trials and changing times – part 1**<br>**Chairperson: Dr Lisa Eckstein** |
| 9:15 – 9:35 | *Trial design – adaptive platform trials*<br>**Professor Steve Webb**<br>Monash University |
| 9:35 – 9:55 | *Structuring your HREC for CT review / panel session (recorded)*<br>**Sally Gordon & Cathy Stevens**<br>Bellberry |
| **9:55 – 10:00** | **Break** |
| **10:00 – 11:30** | **Privacy**<br>**Chairperson: Adjunct Professor Gordon McGurk** |
| | *Privacy essentials [unrecorded session]*<br>**Andrea Calleia**<br>Helios Salinger Privacy |
| **11:30 – 11:45** | **Break** |
| | **Parallel session** |
| **11:45 – 12:45** | **Abstract session: quality assurance [parallel session 1]**<br>**Chairperson: Rob Stanton** |
| 11:45 – 12:00 | *Healthcare quality, mystery shopping and research ethics*<br>**Dr Sharon Schembri**<br>James Cook University |
| 12:00 – 12:15 | *Applying a translational ethics model to facilitate rigorous, high-quality, postgraduate health services research*<br>**Dr Robyn Taylor**<br>South Western Sydney Local Health District |
| 12:15 – 12:30 | *The Victorian Ethics Network: building collaboration and capacity in human research ethics*<br>**Dr Peter Burke**<br>RMIT University |
| 12:30 – 12:45 | *What needs to change to ensure LGBTQ+ people are included in cancer clinical trials?*<br>**Celine Daignault**<br>The University of Sydney |
| | **Parallel session** |
| **11:45 – 13:00** | **Abstract session: quality assurance [parallel session 2]**<br>**Chairperson: Anthony Leicht** |
| 11:45 – 12:00 | *Sharing clinical research results with Australian participants*<br>**Gudrun Wells** |

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| | CT:IQ |
| 12:00 – 12:15 | *Implementation of AI assistant for training of IRB analysts: a novel educational approach*<br>**Chong Xue Jun Jaylynn**<br>NHG Health, Singapore |
| 12:15 – 12:30 | *Redesigning Queensland Health's approach to translational innovation – shining a light on improvement, innovation, evaluation and audit activities*<br>**Beth Wray**<br>Clinical Excellence Queensland |
| 12:30 – 12:45 | *Lived experience people in research design and conduct*<br>**Lisa Treverrow**<br>Australian Institute of Aboriginal and Torres Strait Islander Studies |
| 12:45 – 13:00 | *Research adequacy, AI, and the creation of mHealth Apps*<br>**Dr Dana Wensley**<br>University of Auckland |
| **12:45 – 13:00** | **Break** |
| **13:00 – 14:30** | **Psychedelic drugs in research**<br>**Chairperson: Dr Hudson Birden** |
| 13:00 – 13:30 | *ACT HREC PAT Authorised Prescriber Update and Issues*<br>**Professor Nick Glasgow**<br>Australian National University |
| 13:30 – 14:00 | *A new era for psychedelic-assisted therapy trials: safety, ethics, and progress*<br>**Professor Susan Rossell & Associate Professor Vanessa Beesley**<br>QIMR Berghofer |
| 14:00 – 14:30 | *Treatment using psychedelics – practical and ethical challenges and solutions*<br>**Dr Franklin King**<br>Center for the Neuroscience of Psychedelics, Massachusetts General Hospital |
| **14:30 – 14:40** | **Break** |
| **14:40 – 15:35** | **Clinical trials and changing times – part 2**<br>**Chairperson: Adjunct Professor Gordon McGurk** |
| 14:40 – 15:05 | *Charter for healthy volunteer trials*<br>**Francois Bompart**<br>VOLRETHICS Association, France |
| 15:05 – 15:20 | *Ethics & governance review of adaptive platform trials: practical guidance for HRECs and research officers*<br>**Sophie Gatenby**<br>RCH Melbourne |
| 15:20 – 15:35 | Facilitators and barriers to the clinical trial recruitment of older people: a qualitative study<br>**Sue Markham**<br>University of Sydney |
| **15:35 – 15:40** | **Break** |

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| **15:40 – 16:40** | **HREC member panel discussion**<br>**Chairperson: Kate Henderson** |
| | *Role and challenges for HREC members*<br>*Panellists:*<br>**Alison Bradshaw**<br>Central Adelaide Local Health network<br>**Lucy Lopez**<br>The University of Queensland HREC<br>**David Luttrell**<br>RPA HREC<br>**Geoff Vass**<br>Women's and Children's Health Network HREC |
| **17:00** | **Close** |

# Day 3 – Thursday 27 November 2025

All times in AEST (QLD)

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| **8:00 – 09:20** | **Regulation & legislation**<br>**Chairperson: Adjunct Professor Gordon McGurk** |
| 8:00 – 8:20 | *Building a new framework for research tissue regulation in Australia: the Australian Law Reform Commission's proposals for reform*<br>**Dr Meaghan Toews**<br>Australian Law Reform Commission |
| 8:20 – 8:35 | Update: quality standards and accreditation scheme for HRECs and their host institutions<br>**Michael Swarbrick**<br>Australian Government Department of Health, Disability and Ageing |
| 8:35 – 8:50 | *TGA update on psychedelic assisted therapy*<br>**Professor Robyn Langham**<br>Therapeutic Goods Administration |
| 8:50 – 9:05 | *TGA principles to practice: governance, regulation and compliance for AI-enabled human research*<br>**Bridgette Basnayt**<br>University of Southern Queensland |
| 9:05 – 9:20 | *Chair discussion & question time* |
| **9:20 – 9:30** | **Break** |
| **9:30 – 11:15** | **Operationalisation & quality assurance**<br>**Chairperson: Lindsey MacDonald** |
| 9:30 – 9:50 | *The canReview Project*<br>**Susan Marlin**<br>Clinical Trials Ontario |
| 9:50 – 10:10 | *Research our way: exploring the ethics governance experiences and preferences of Aboriginal and Torres Strait Islander community controlled health organisations and HRECs of Queensland [unrecorded session]*<br>**Greg Pratt**<br>Central Queensland University, QAIHC |
| 10:10 – 10:30 | *Beyond tokenism: recruiting for and sustaining equitable representation on a Northern Territory Human Research Ethics Committee*<br>**Hayley Germaine**<br>Charles Darwin University |
| 10:30 – 10:45 | *STILETTO: SupporTIng quaLity EThics applications & timely respOnses*<br>**Dr Sarah Moberley**<br>Hunter New England Local Health District |
| 10:45 – 11:00 | *Data sharing for secondary research in Australia: results from a Shared Ethical Debate (ShED) exercise*<br>**Dr Rebekah McWhirter**<br>Australian National University |
| 11:00 – 11:15 | *Redefining the boundaries: research, quality activities and clinical registries*<br>**David O'Halloran**<br>Department of Health Tasmania |

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| **11:15 – 11:30** | **Break** |
| **11:30 – 13:00** | **Community-minded research**<br>**Chairperson: Dr Janelle Bowden** |
| 11:30 – 11:50 | *Community-based participatory research (CBPR)*<br>**Associate Professor Adam Becker**<br>Northwestern University Feinberg School of Medicine |
| 11:50 – 12:10 | *Pre-ethics: Relational groundwork for ethical encounters [unrecorded session]*<br>**Sebastian J. Lowe**<br>Aarhus University, James Cook University |
| 12:10 – 12:25 | *Ethical gaps in the inclusion of people with dementia in self-advocacy: beyond research protocols*<br>**Kate Swaffer**<br>University of South Australia |
| 12:25 – 12:40 | *"Do we need ethics for that?" A provocation from a project to grow James Lind Alliance Priority Setting Partnerships in Australia*<br>**Dr Bec Jenkinson**<br>The University of Queensland |
| 12:40 – 13:00 | *Involving people with disability as consumer research partners*<br>**Associate Professor Margaret Wallen**<br>Australian Catholic University |
| **13:00 – 13:15** | **Break** |
| | **Parallel session** |
| **13:15 – 14:15** | **Abstract session: clinical trials and consent [parallel session 1]**<br>**Chairperson: Natasha Roberts** |
| 13:15 – 13:30 | *Advancing health equity in randomised controlled trials: a collaborative implementation science approach*<br>**Mark Liu**<br>The University of Queensland |
| 13:30 – 13:45 | *The role of familial carers in palliative care for terminal cancer: the ethics of autoethnography*<br>**Associate Professor Susan Hemer**<br>University of Adelaide |
| 13:45 – 14:00 | *Consent-to-continue in intensive care clinical trials: a mixed-methods scoping review and recommendation for reporting [unrecorded session]*<br>**Renate Le Marsney**<br>The University of Queensland |
| 14:00 – 14:15 | *Enabling decentralised clinical trials in NSW and ACT*<br>**Anna Hartley**<br>Cancer Institute NSW |
| | **Parallel session** |
| **13:15 – 14:15** | **Abstract session: clinical trials and consent [parallel session 2]**<br>**Chairperson: Anthony Leicht** |
| 13:15 – 13:30 | *Inclusivity in informed consent*<br>**Natalie Day**<br>Parenting Research Centre |

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| 13:30 – 13:45 | *Simplifying consent: a user-centred approach for people with schizophrenia*<br>**Gabrielle Ritchie**<br>The University of Queensland |
| 13:45 – 14:00 | *Consent and command: ethical dilemmas of studying the military*<br>**Ofelia Carreno**<br>University of Adelaide |
| 14:00 – 14:15 | *Increasing CALD recruitment in cancer clinical trials by engaging interpreters and clinical trial staff*<br>**Dr Suzanne Grant**<br>Western Sydney University |
| **14:15 – 15:15** | **HREC chair debate**<br>**Chair: Adjunct Professor Gordon McGurk** |
| | *Panellists:*<br>**Professor Michael Martin**<br>**Associate Professor Mandy Downing**<br>**Associate Professor Suzie Ferrie**<br>**Professor Andrew Crowden** |
| **15:15 – 16:15** | **Conference closing remarks** |
| 15:15 – 15:45 | *The Rob Loblay Oration*<br>**Associate Professor Stephen Adelstein**<br>Royal Prince Alfred Hospital \| Central Sydney Immunopathology Laboratory \| NSW Health Pathology \| RPA Institute for Academic Medicine \| University of Sydney |
| 15:45 -16:15 | *Rob Loblay Award*<br>Presented by **Associate Professor Suzie Ferrie**<br>Sydney Local Health Department |
| **16:15** | **Close** |

# Abstracts & biographies

## Tuesday 25 November 2025

### 10:00 – 10:30 Conference opening

**Presenters**

**Adjunct Professor Gordon McGurk**
Gordon has a long history in the research and government sectors. He spent 15 years as an executive in the Australian public service, most recently working in the areas of policy development and implementation. His research experience is particularly in the areas of clinical trial and research governance. Gordon is a Fellow of the Governance Institute of Australia, a Graduate of the Australian Institute of Company Directors, a former Director of the Association of Biosafety Australia and New Zealand, and currently chair of an Australian Standards sub-committee on biosafety. He chairs 2 HRECs in Brisbane. He is also a qualified lawyer with an interest in health and human rights law.

**Dr Lindsey Te Ata o Tū MacDonald**
Lindsey is a senior lecturer in political philosophy and a research associate of the Ngāi Tahu Research Centre at the University of Canterbury.

His early career was in New Zealand's State Services (now Public Service) Commission and Te Puni Kōkiri (Ministry of Maori Development). He completed his PhD while lecturing in the Māori and Political Science departments at the University of Canterbury. As part of his public service, he was on the National Ethics Advisory Committee (2021-25), where he acted as Deputy Chair for the last 2 years, and he was a Co-Chair on the Health Research Council Ethics Committee (2023-25). He is also Co-Chair of the Aotearoa Research Ethics Trust, which provides research ethics review for community researchers, and founded the independent human research ethics collective, which provides research ethics review for government and commercial researchers.

Lindsey researches and publishes on indigenous political voice, self-determination, property rights, and democracy in the Asia-Pacific. He also works with colleagues across the research sector on various projects. Recently, these have included farming and sustainability, tobacco control, and research ethics.

**Associate Professor Stephen Adelstein**
Stephen is Head and Senior Staff Specialist of the Department of Clinical Immunology and Director of the Central Sydney Immunology Laboratory at Royal Prince Alfred Hospital. He is also an Associate Professor of Medicine at the University of Sydney's Medical School.

A practitioner member of the Medical Board of Australia, Stephen has been involved in medical regulation since 2008, serving on the New South Wales Medical Board and as a past member of the Medical Council of New South Wales. He currently serves on NSW Health Pathology's Research and Innovation Committee, as well as on the Medical Board of Australia's National Registration Assessment Committee and Medical Training Survey Advisory Group.

In addition to his clinical and academic practice, he oversees undergraduate and postgraduate research. He also serves on a range of governance committees, including the Management Committee of the Institute of Personal Medicine and Bioinformatics, Sydney Local Health District and Intellectual Property Committee, Royal Prince Alfred Hospital. He has been a member of the Australian Health Ethics Committee since 2018.

**Dr Elizabeth Fenton**
Elizabeth is a senior lecturer in the Bioethics Centre at the University of Otago and current Chair of the National Ethics Advisory Committee. She was previously a Fellow in the Program in Ethics

and Health at Harvard University, and a senior policy and research analyst at the US Presidential Bioethics Commission. Her research focuses on ethical issues in public health, global health, and health policy.

**Greg Pratt**
Descendant of the Quandamooka people of Moreton Bay, Greg grew up with the Ghughu Yalanghi people of Cape York. He has extensive experience as an Aboriginal mental health practitioner and has worked in policy, research and health services. Greg led extensive consultations across Queensland in 2018 for GenetiQs, developing guidelines for genomic research involving Aboriginal and/or Torres Strait Islander peoples. In 2019, he led efforts to develop a suite of genomic health literacy resources for First Nations peoples of Queensland. In 2020-21, his team worked with community controlled, primary and public health services to identify workforce needs for a coordinated care model for precision medicine at the primary health intersect.

He is also principal investigator on a suite of research projects in the mental health and social and emotional wellbeing field. Over the past 3 years, Greg has led more than 80 community engagements across Queensland. He is passionate about and committed to supporting the research sector to realise its responsibility to benefit and empower Aboriginal and Torres Strait sovereignty, equity and equitable access to health and health research.

| **10:30 – 11:15** | **Plenary** |
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*Agentic AI – Its impact on health & ethics*
**Aaron Zamykal**
Actualisation

**Abstract**
Agentic AI is changing the world. Imagine employing a private team of specialists' agents that work together on a common goal – without downtime. This is now a reality. We need to consider how the health industry can benefit from these agentic AI teams, and what ethical constraints we need to consider. In this session we will discuss what AI agents are, what agentic AI is, and how the health industry can apply this technology to complement human endeavour.

**Biography**
Aaron is the founder and CEO of Actualisation, one of Australia's largest privately owned artificial intelligence (AI) firms. Founded over 10 years ago in Australia, it has now 4 offices around the world and over 120 team members. Actualisation designs, trains and deploys private AI factories and agentic AI teams for companies who want to take advantage of its benefits. Right now we are experiencing more technological change than Aaron has seen in his 25 years in business. Drawing on his experience in several industries, Aaron is constantly making sense of what is happening in the current climate. He believes we are at a pivotal moment in time where traditional methods are becoming obsolete and new ways of thinking are required. Aaron has a young family that keeps him energised and motivated to create an amazing life.

| **11:15 – 12:30** | **Technology & AI** |
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11:15 – 11:35
*Would we want generative artificial intelligence in institutional review boards?*
**Joel Seah**
NUS, Singapore

**Abstract**
Research ethics committees – such as Institutional Review Boards (IRBs) – are charged with the moral remit of protecting the rights, safety and welfare of participants involved in human subjects research (HSR). Importantly, unlike other types of ethics committees (e.g. hospital ethics committees), IRBs are empowered by regulations to make legally binding ethical judgements through their reviews, requirements (e.g. protocol modifications), and decisions (i.e. approvals or disapprovals) in their oversight of HSR.

Despite their relatively brief 50-year history, IRBs today face various persistent challenges – and no shortage of criticism and scholarly debate – not only in the efficiency of their review processes but, more concerningly, in their ability to effectively fulfil their ethical mandate. These issues include: (i) inter- and intra-variability in the standard and quality of their ethical analysis, reasoning, and decision/judgements; (ii) a lack of institutional memory of past deliberations and justifications (i.e. precedent); and (iii) insufficient ethical expertise within their membership compositions to accurately identify, engage, and weigh competing moral considerations. In other words, IRBs are lacking – in their ethical judgements – consistency, and depth and quality in their moral reflections and deliberations.

This presentation presents a novel prospect of how Generative Artificial Intelligence (GenAI) tools, e.g. Large Language Models, agentic AI, could support or augment IRBs in achieving contextual consistency, and applying ethical analysis, interpretation, and reasoning in their decision-making to enhance the effectiveness of their oversight, and rigour and standard of their deliberations and judgements.

Presupposing that hybrid human-GenAI IRBs do prove to be more 'effective' than human-only IRBs, the presentation raises several ethical concerns that warrant IRBs to adopt a cautious and considered approach to GenAI utilisation, including deskilling, authoritative fallacy, epistemic authority, and questions of accountability and trust in AI-assisted ethical reviews.

**Biography**

Joel is a PhD candidate at the Centre for Biomedical Ethics, National University of Singapore, and a biologist by training. A former Human Research Protection Programme (HRPP) professional, he has held roles as an analyst and manager at the Institutional Review Boards (IRBs) of National Healthcare Group, Singapore Management University, and Nanyang Technological University. He is a member of the Consortium to Advance Effective Research Ethics Oversight (AEREO) which seeks to improve HRPP/IRB effectiveness, and a task force member of the Framework for Review of Clinical Research Involving AI co-developed by the MRCT Center and WCG Clinical. Joel's current interests lie in AI, data, research ethics, and AI-human interactions. His doctoral work focuses on the role of Generative AI/Large Language Models (GenAI/LLMs) in research ethics oversight.

## Technology & AI

11:35 – 11:55

*AI = All In? How can HRECs address the 'new research normal'?*

**Professor Michael Martin**

Australian National University, Australian Health Ethics Committee

**Abstract**

The ubiquity of AI tools such as LLM chatbots and machine learning algorithms has ushered in a 'new normal' for researchers, who have embraced these tools as both a research accelerant and as a means for enhanced discovery. But AI tools pose ethical challenges that raise issues such as transparency and explainability of AI methodologies, authorship and accountability for content generated with the assistance of AI, data governance and sovereignty, bias and fairness in the data used to train AI models, and for fundamental principles such as free, prior and informed consent. The Australian Health Ethics Committee is supporting NHMRC by developing guidelines for HRECs assessing research involving AI. This talk will describe the present state of these proposed guidelines, the issues underpinning their development, and the challenges that HRECs must address as we enter the 'new research normal'.

**Biography**

Michael is Professor of Statistics in the Research School of Finance, Actuarial Studies and Statistics at the Australian National University in Canberra, Australia. He holds a Bachelor of Science (Hons) degree from The University of Queensland (1986) and a PhD in Statistics from the ANU (1989). He was Assistant Professor of Statistics at Stanford University, USA, from 1989 to 1992 and Annenberg Distinguished Assistant Professor in Statistics at Stanford from 1992 to 1994. He joined the ANU as Lecturer in Statistics in 1994, becoming Professor in 2007, a position he continues to hold. He is an elected member of the International Statistical Institute (ISI), Fellow of the Royal Statistical Society (UK), and has been honoured as a Fellow of the

American Statistical Association for his services to research and teaching in Statistics. He is Principal Fellow of the Higher Education Academy (UK), and in 2017, he was selected as an ANU Distinguished Educator.

He has over 75 publications in peer-reviewed journals, publishing extensively in both theoretical and applied statistics, including applications to medicine (in particular breast cancer), population health and environmental science (air pollution mortality). He recently co-edited (with Professor Bruce Smyth and Associate Professor Mandy Downing) The Routledge Handbook of Human Research Ethics and Integrity in Australia, published in late 2024. His contributions to higher education include as highlights a Carrick Citation for Contributions to Teaching and Learning in 2007, and a Carrick Award for Teaching Excellence, also in 2007, each awarded within the Australian Awards for University Teaching.

He has served on HRECs at the ANU since 2006, as Chair of the Humanities and Social Science Delegated Ethics Review Committee from 2012 to 2015, Chair of the Science and Medical Delegated Ethics Research Committee from 2014 to 2015 and as Chair of the ANU HREC from 2015 to 2024. He is presently a member of the Australian Health Ethics Committee (AHEC) under the auspices of the NHMRC for the 2024-2026 triennium.

## Technology & AI

11:55 – 12:15

*Human-in-the-loop: balancing innovation and accountability in law enforcement use of AI*

**Dr Andrew Chen**
New Zealand Police

**Abstract**
New Zealand Police publicly released its Acceptable Use of Generative AI Policy in early 2025, setting the foundations for the use of tools such as Copilot Chat across an organisation of 15,000 people. This talk will present some context around NZ Police, and then discuss some of the key elements of the policy and how they have been considered in the high-stakes law enforcement space.

**Biography**
Dr Andrew Chen trained as a computer engineer with a PhD in Computer Systems Engineering from the University of Auckland, specialising in AI and machine learning. His most recent role is as Chief Advisor, Technology Assurance, with New Zealand Police, providing expertise on the legal, privacy, security, and ethical considerations of police use of new technologies such as facial recognition, open source intelligence, and artificial intelligence.

## 12:40 – 13:55 Consent & consent forms

12:40 – 13:00

*Social media and ethics review: identifying potential scandals & protecting participants*

**Professor Paula Swatman**
Bellberry

**Abstract**
In this age of AI, the topic of social media ethics review may seem a bit old-fashioned – after all, the 2018 update of the National Statement covered the topic fully, didn't it? Social media remains a huge influence on people from every walk of life and every lifestyle, so it's not surprising that influencers want to test just how effectively they can manipulate public opinion on these monster platforms, or make use of the mountain of data collected from willing participants to investigate (or influence) a wide range of medical and social issues. So how do ethics committees – both HRECs and, potentially, even low-risk committees – review social media research effectively, so that those who trustingly post their data and deepest feelings can be protected from overly intrusive unethical research?
This presentation will briefly survey some of the most egregious misuses of social media activity and data over the past few years, before discussing how ethics reviewers might realistically counter the risks and pitfalls in this area.

**Biography**
Paula is a retired Professor of Information Systems who specialised in researching how bleeding-edge technology was adopted and used by both organisations and individuals, starting with EDI and the evolving world of e-commerce to social media and, most recently, AI over 40 years. She has a significant interest in human research ethics and, following Category F membership of HRECs at Monash, RMIT, UniSA and UTAS. Paula was Chair of the Tasmanian Social Sciences HREC (2012-2016); Chair of Swinburne University's HREC (2016-2024); and has been a Category F HREC member with Bellberry Limited since February 2016. At the start of 2025 she also became a Deputy Chair at Bellberry and chairs their low-risk sub-committee. Paula has a particular interest in the ethical issues associated with online research and social media and AI, an area in which she has been presenting and publishing for some years now.

## Consent & consent forms

13:00 – 13:15
*Can 16- and 17-year-olds give consent to participate in research without parental consent?*
**Professor Richard Gray**
La Trobe University

**Abstract**
Informed consent is a foundational principle in human research. In Australia, the National Statement on human research considers children and young people (those under the age of 18 years) to be a group that raises 'particular ethical concerns'. The Statement suggests that young people's ability to understand research and make an informed decision to participate cannot be determined by age. Rather researchers need to decide if young people have the maturity and capacity to consent.

Over the course of 2025 La Trobe University's HREC has received several applications to approve studies involving groups of young people where parental consent will not be sought, challenging to consider how we make such decisions in the best interests of the young people participating in the research. The case researchers have made in these applications can essentially be distilled to a single argument: that there is research demonstrating that 16- or 17-year-olds have capacity and can give informed consent. Essentially, researchers have argued, contrary to the Statement, that capacity can be determined by age.

This paper will discuss how HRECs should approach such applications, taking into account the merits of allowing groups of young people to consent to participate in human research when weighed up against the possible harms and/or potential objections of parents/guardians. The aim is to provide helpful and informative guidance to HRECs that may also be facing this important issue.

**Biography**
Richard has been at La Trobe University since 2017, becoming Chair of the HREC in 2024. He was educated and worked as a mental health nurse at the Maudsley Hospital in London before training in epidemiology and public health at the London School of Hygiene and Tropical Medicine. Subsequently, he has worked as a mental health services researcher primarily focused on improving physical health outcomes for people experiencing mental ill-health, initially at the Institute of Psychiatry, King's College London and latterly at the University of East Anglia and La Trobe University. His work has directly impacted health policy and practice for people experiencing mental ill-health in Australia and internationally. He is editor-in-chief of Nursing Reports and is actively involved in the open science movement.

## Consent & consent forms

13:15 – 13:35
*The InFormed Project*
**Dr Lisa Eckstein & James Cokayne**
CT:IQ & NSW Ministry of Health

**Abstract**
Participant information and consent forms (PICF) are crucial to respecting participant autonomy in health and medical research. However, unfortunately, these forms are often unduly long, legalistic, and written at levels that exceed the health literacy levels of many participants. Through a consultative process, the CT:IQ InFormed Project has developed a shorter participant-centred PICF, which is currently being implemented by sites, HRECs and government departments. This presentation will cover the process of developing the InFORMed template, key principles for use, and current implementation activities.

**Biography**
Lisa is the CT:IQ Programme Director and Ethics Specialist for Bellberry Ltd. Her previous role was as a senior lecturer in the Faculty of Law at the University of Tasmania, where she chaired the Tasmania Health and Medical HREC and published on the regulation of clinical trials, genomic privacy, and consent. Prior to academia, Lisa worked as a legal officer for the Australian Law Reform Commission and for state and federal health departments.

James leads the Research Ethics and Governance Unit and the REGIS team at the NSW Office for Health and Medical Research (OHMR). With a medico-legal background he has worked extensively within the NSW Public Health System. He has also had significant involvement in the private health, university and non-government sectors. At OHMR, he is the NSW delegate on the NMA Jurisdictional Working Group, part of the NSW delegation at the Inter-Governmental Policy Reform Group (IGPRG) and before that on the Clinical Trials Project Reference Group (CTPRG) and has recently stepped down after 10 years as Chair of the SEBS (now NaCTA) Panel. He is the NSW Health Advisor for research policy-related queries for Ethics, Governance, Insurance and Indemnity in Clinical Trials, Guardianship, Human Tissue and the Early Phase Clinical Trial HREC Framework. He is also the primary contact for Animal Ethics issues within NSW Health. James has bachelor's degrees in Law (LLB)(Hons) and Health Information Management (HIM) and a master's degree in Health Law (MHL).

## Consent & consent forms

13:35 – 13:55
*What can HRECs learn from the ShED project: waivers, secondary data usage, exemptions and HREC quality assurance*
**Adjunct Professor Gordon McGurk**
Southern Cross University

**Abstract**
In 2025, CT:IQ and ARDC conducted an exercise to assess how HRECs reviewed a mock application for the use of data for potentially secondary purposes. The mock application included dome tantalising facts and left HRECs to decide how they would treat it. This talk considers the decision-making process and the application of the National Statement and reflects on the value of such a quality assurance exercise.

**Biography**
See page 14.

## 14:05 – 15:30 Data management

14:05 – 14:25
*Using personal information in research: some recent legal cases*
**Sonja Read**
MinterEllison

**Abstract**
This session will cover the following topics:

- Using personal information in research: some recent legal cases
- Use of de-identified information in research
- What steps are necessary to de-identify data?
- The role of HRECs in reviewing studies using de-identified information.

**Biography**
Sonja is a Partner at MinterEllison, advising clients in the health and life sciences sectors on regulatory compliance and privacy. She has been a legal member of HRECs for 15 years.

## Data management

14:25 – 14:45
*Creepy or just complex? Making ethical decisions in a messy world*
**Emma MacDonald**
Stats NZ

**Abstract**
In a world of accelerating AI adoption and data-driven decision-making, we need a strong, evolving culture of ethics. At the heart of data ethics is a simple truth: every data point represents a person, and often someone vulnerable. Putting people first is no longer optional, it is essential.

This session introduces the Human Values for Data Ethics framework, developed by Stats NZ's Centre for Data Ethics & Innovation (CDEI). These 6 human values help people, especially non-specialists, engage with data ethics in a way that's practical and human. They offer a shared language for navigating complexity and making space for the gnarly, necessary conversations that responsible data use requires. A simplified, flexible approach to ethical thinking that puts people at the centre and is to understand, communicate, and apply no matter your experience.

Coming from Aotearoa, part of the data ethics conversation will always be recognising data as taonga, understanding Māori data sovereignty, and affirming Māori rights to control, protect, and benefit from their data. We believe this is the gold standard for all.

Drawing on lived wisdom and community perspectives, this session explores what a pragmatic and distinctly human approach to data ethics looks like, because in the fast-paced world of AI, ethics must keep up. When ethical thinking is embedded across all levels and sectors, we innovate more safely, identify risks earlier, and protect people.

**Biography**
Emma is the Director of the Centre for Data Ethics and Innovation (CDEI) at Stats NZ. CDEI's aim is to help the public service navigate the complex ethical challenges of data use and is focused on practical solutions and recognising ethics isn't about perfection, it's about thoughtfulness and balancing competing priorities.

Although not a data scientist by training, Emma has spent much of her career working alongside data experts and scientists. She brings deep experience as a policymaker, with a particular focus on the social impacts of digital innovation. Her work is grounded in a commitment to ensuring that data-driven technologies serve the public good.

## Data management

14:45 – 15:00
*New horizons: a draft governance framework for synthetic health data in Australia*
**Keren Pointon, Carly Olsen & Dr Amir Marashi**
Digital Health CRC

**Abstract**
The use of synthetic health data (artificially generated datasets that mimic real-world health information) is gaining traction in Australia, though in a slower and more uneven way than many expected. Researchers, policymakers, and health services see its potential for improving access to timely and secure information, yet questions about governance and trust including privacy and data security continue to hold back widespread adoption. Synthetic datasets can closely resemble real health records while protecting individual privacy, but they are not a simple fix to the long-standing problems of data sharing.

This presentation outlines a draft governance framework developed through the SynD community of practice—a national network involving researchers, health departments and universities. While the framework draws on international examples, it has been shaped most strongly by local workshops and discussions considering local jurisdictions. It centres on principles such as ethical stewardship, transparency, and trust, but it also grapples with more practical matters: data quality standards, privacy guardrails, approaches to risk management, and mechanisms for accountability.

The presentation emphasises that this is not a final model. It is an early attempt that highlights both areas of consensus and points where disagreement remains. The presentation will share insights from the collaborative process and reflect on how synthetic data governance intersects with broader ethical and regulatory debates in human research.

It is hoped to use feedback from the HREC community and other stakeholders to refine the framework through further workshops, case studies and practical trials, with the longer-term aim of building a credible and consistent pathway for the responsible use of synthetic health data in Australia.

**Biography**

Keren is a leader in health care improvement bringing extensive lived experience as a health consumer, combined with a Master of Public Health and business experience as a CPA to help advocate for and deliver health system change. Through her health consulting and contracting engagements, her expertise spans digital health initiatives, health system governance, value-based health care, benefits analysis, patient safety and quality assurance, health care funding reform, and health research management. She has a proven track record in driving process improvement and steering organisational governance, always with the imperative "how does this help the patient?".

Carly is a Senior Project Officer with the Department of Health (WA Health) and assists with the development, management and delivery of strategic projects undertaken as part of the WA Health Data Linkage Strategy and Reform program. She is responsible for providing accurate and timely advice on project progress, emerging risks and issues, while also providing necessary expertise in communications and stakeholder engagement.

Amir is a health data scientist specialising in machine learning, synthetic data, and digital health innovation. He holds a PhD in predictive modelling on health data. His work focuses on privacy-preserving synthetic data pipelines, governance frameworks, and translating AI research into real-world health care applications. Amir brings a unique blend of technical expertise and strategic insight to digital health, with a strong commitment to making data more secure, accessible, and impactful. Outside of work, he enjoys Persian calligraphy, origami, and delving into the intersections of conscientiousness and philosophy.

## Data management

15:00 – 15:15

*Embedding Indigenous Data Sovereignty principles across organisational research practice: practical strategies for ethical governance and community benefit*

**Nicole Hewlett & Imelda Ryan**
Mater Research

**Abstract**

This presentation outlines a whole-of-organisation approach to embedding Aboriginal and Torres Strait Islander equity and Indigenous Data Sovereignty (IDS) principles across research governance, design, and implementation. Through a series of coordinated activities, Mater Research is actively reframing colonial deficit-based research paradigms and shifting towards strengths-based, community-led research practice.

Key initiatives include the appointment of an Aboriginal Research Liaison Advisor, the development of internal guidelines for applying IDS principles, and capacity-building programs and resources for researchers and clinicians. These programs support staff to engage ethically and respectfully with Aboriginal and Torres Strait Islander communities, apply culturally

responsive methodologies, and ensure data is governed, interpreted and shared in ways that uphold community sovereignty and self-determination.

This approach challenges traditional research models that often position Indigenous communities as subjects of inquiry, instead centring Indigenous knowledge systems, governance, and lived experience. By embedding IDS principles, we are transforming how research is conceptualised, conducted, and translated—ensuring it benefits communities at the grassroots level and reflects their priorities.

For HRECs, this presentation offers practical strategies to assess applications involving Aboriginal and Torres Strait Islander peoples, including indicators of respectful engagement, governance, and community benefit. It also explores how IDS principles intersect with secondary data use, consent processes, and the engagement of lived experience in research design.
By reframing research ethics through an Indigenous equity lens, we are modelling a transformative approach to research governance. This presentation will provide HREC members with tools to support culturally safe, community-driven research and ensure that ethical review processes uphold the rights, self-determination and sovereignty of Aboriginal and Torres Strait Islander peoples.

**Biography**
Nicole is a proud Palawa mother of 2 daughters, based in Meanjin on the sovereign and unceded lands and waters of the Turrbul and Yuggera peoples. She works in a knowledge translation role at La Trobe University and as an Aboriginal Research Liaison advisor at Mater UQ. She is in her last year of her PhD and co-founded the National Aboriginal and Torres Strait Islander Palliative Care Association Inc. Nic is passionate about drawing on the profound strengths of Aboriginal cultures and local ways of knowing, being and doing to support healing pathways that bring genuine and meaningful benefit to Aboriginal and Torres Strait Islander families at a grassroots level.

Imelda is the Senior Manager of Research Compliance at Mater Research, where she leads the Ethics, Governance, Research Agreements, and Research Quality teams across Mater's Queensland hospitals. Originally trained and working as a medical librarian, Imelda brings a unique perspective to research management, combining deep expertise in information systems with extensive experience in research governance, clinical trials, and strategic policy development. She has led statewide initiatives for Queensland Health, including the RAPID Project (improving research approval pathways), DoRA 2.0 (Database of Research Activity), and the Clinical Trials Queensland platform. Imelda holds postgraduate qualifications in management and information science and has held senior roles across Queensland Health, Children's Health Queensland, and Gold Coast Health.

## Data management

15:15 – 15:30
*But who owns the data? A case study from the evolving digital health landscape*
**Liesel Higgins**
CSIRO

**Abstract**
Seeking approval for data usage can be fraught with challenge. However, when that data is mixed with an evolving digital health landscape, new innovations in digital technologies, and a legacy consent process, it is likely that both researchers and governance officers will be heard to shout, "But who owns the data?".

This presentation outlines the ethical and governance considerations and challenges associated with approving data linkage, of an externally hosted digital research data portal, with a hospital dataset. In 2015, Redland Hospital at Metro South Health, and CSIRO conducted a small feasibility trial of 40 women with gestational diabetes mellitus (GDM). This trial was aimed at understanding if using a digital diary instead of a paper-based diary, to record daily blood glucose levels, was feasible. The digital health care environment, the governance consent requirements and privacy considerations of using a digital platform were new and innovative. No

one could predict that this small idea would become a large implementation trial with the technology being used with over 12,000 women across Redland, Logan, Royal Brisbane and Women's, Cairns Base, and the Mater public hospitals.

Given the success of the project, the research team decided in 2023, to measure the cost consequences of this project. However, it was unclear to both research governance at each Hospital and Health Service site, and to the CSIRO researchers, who the appropriate data custodian was for the MoTHer platform. While in today's research projects, it is known that data custodians must be identified from the outset of a project, this was not the case in the earlier days of the MoTHer projects when consents were established. For both the researchers and the research governance teams, this question was a challenge to answer, and both parties had to collaborate to problem solve the answers.

This presentation will outline the unique set of challenges that this project presented; what was concluded and how the consultation was reached; and key lessons which will apply to these types of research projects into the future. With increasing amounts of digital technology being researched and evaluated, the learnings from this presentation will be useful for all researchers, governance bodies, and decision-makers.

**Biography**

Liesel is a Project Manager and Team Leader with the Digital Therapeutics and Care group. Liesel has a clinical background and is experienced in developing, delivering, and evaluating research projects related to digital technologies, specifically sensor technologies, smart home applications, and mobile health platforms. She has been involved in research across acute and chronic care, disability and aged care and currently leads the aged care stream of research within the AEHRC. Liesel has been involved with project management aspects of the Gestational Diabetes Mellitus MoTHer platform since it was conceptualised in 2015 as a pilot project between the AEHRC and Metro South Health. Liesel has watched the evolution of the data management aspects of MoTher over the past 10 years.

| **15:40 – 16:55** | **Operationalisation & quality assurance** |
|---|---|

15:40 – 16:00

*Brief overview of changes to National Statement*

**Jeremy Kenner**

NHMRC

**Biography**

Jeremy is the expert advisor for ethics to the NHMRC's Research Quality and Advice Branch. At the NHMRC, he is responsible for or contributes to a broad range of programs and projects related to health and research ethics, governance of research and clinical trials and provides advice internally and externally on these matters. Prior to his current role, Jeremy served as Ethics Coordinator at the Peter MacCallum Cancer Centre in Melbourne. Earlier in his career, Jeremy worked as a school teacher, practiced law, and conducted public education and research in bioethics in the US. His academic background is in anthropology, theology and law.

| | **Operationalisation & quality assurance** |
|---|---|

16:00 – 16:20

*Ethics of advising*

**Associate Professor Monique Jonas**

University of Auckland

**Abstract**

Monique is an Associate Professor at Waipapa Taumata Rau, University of Auckland's School of Population Health. She has a PhD in Medical Ethics from Kings College London. Her research spans a wide range of ethical concerns connected with health, decision-making and the relationship between the family and the state. She teaches ethics within the medical programme and the Bachelor of Health Sciences and has served on New Zealand's National Health

Committee, National Ethics Advisory Committee and Health Research Council Ethics Committee. Her recent book The Ethics of Advising is available from Oxford University Press.

**Biography**
Advising researchers is a common aspect of research ethics committee and secretariat work, but it can pose ethical challenges that are difficult to define. Drawing on Professor Jonas' account of 5 norms of advising, the session will explain why advising can be in tension with the regulatory and permissioning functions of an ethics committee, and open discussion about ways of managing this tension.

## Operationalisation & quality assurance

16:20 – 16:35
*Revisiting the 2024 Declaration of Helsinki: critiques and implications for human research ethics review*
**Dr Ehsan Shamsi Gooshki**
Monash Bioethics Centre

**Abstract**
The 2024 revision of the Declaration of Helsinki (DoH), released 6 decades after its original adoption by the World Medical Association in 1964, marks a significant evolution in international ethical standards for human research. This paper critically examines key changes introduced in the new version, with particular attention to their implications for HRECs. Notable shifts include the replacement of the term *research subjects* with *research participants*, and an expanded scope of moral accountability beyond physicians to include all stakeholders involved in research practice.

The paper also explores critical concerns raised by scholars and ethicists regarding the 2024 version's continued emphasis on conventional clinical trial models. Topics such as post-trial access remain narrowly framed, leaving insufficient guidance for non-traditional research contexts—including AI-driven studies and observational or non-interventional research.

Additionally, the DoH's cautious stance on the concept of social value in research is analysed for its ethical implications, particularly in relation to the justification of placebo-controlled trials and global research conducted in low-resource settings. By highlighting both the progress and the limitations of the updated Declaration, this paper contributes to an ongoing dialogue about its adequacy and applicability in a rapidly evolving research landscape.

**Biography**
Ehsan is a physician (M.D.) and bioethicist (Ph.D.) with nearly 20 years of experience in teaching, research, and leadership across diverse areas of bioethics, including research ethics, clinical ethics, public health ethics, governance, and global health ethics.

In academia, he has served as Associate Professor of Medical Ethics at Tehran University of Medical Sciences. Since 2023, he has been Lecturer at the Monash University Bioethics Centre and, from 2025, Coordinator of the Medical Ethics Program. He has authored numerous articles in leading journals and supervised many postgraduate theses in bioethics. He has also held fellowships at the University of Zurich, Switzerland and Georgetown University's Kennedy Institute of Ethics, USA.

In the field of bioethics governance and implementation, Ehsan has held several senior positions in Iran, including Secretary of the National Committee for Ethics in Biomedical Research, Senior Advisor and Secretary of the Medical Ethics Committee at the Iran Medical Council, and Secretary of the Medical Ethics Group at the Iran Academy of Medical Sciences. In these roles, he was instrumental in developing national systems for research, clinical, professional, and public health ethics, as well as drafting the Iran Medical Council Code of Ethics and the Healthcare Professionals' Charter of Rights.

Internationally, he has collaborated with major organisations including WHO, UNESCO, ICRC, and WMA. He has worked with the WHO Department of Health Ethics and Governance since

2010 and contributed to activities of WHO's Western Pacific (WPRO) and Eastern Mediterranean (EMRO) regional offices. He is currently Consultant and Lead Writer of WHO's clinical ethics guidance, Vice-Chair of the WHO Ethics Review Committee, and a member (Vice-Chair since 2023) of UNESCO's International Bioethics Committee.

## Operationalisation & quality assurance

16:35 – 16:55

*Crossing the line: the contested space between quality and research*

**Rachel Kerr**
Monash University

**Abstract**

In Victoria, multi-site collaboration for quality and research are impacted by the devolved health care model and differing interpretations of legislation and guidelines between institutions. The Bridging Research and Quality (BRaQ) initiative aims to reduce ambiguity and inefficiency in the oversight of evaluation, improvement, and low-risk research activities. Through the work of a collaborative community of practice composed of consumers, community members, policy makers and public and private health services, the project will establish regulatory process into routine care. Achieving this will support a vibrant and efficient learning health system approach across the health sector.

Using a co-designed, collaborative implementation approach, BRaQ engaged stakeholders from research, quality, legal, data, and consumer groups. At the Summit, participants initiated the development of a shared purpose and guiding principles to support proportionate, ethical oversight of improvement initiatives. A key theme was the need for clearer delineation of pathways—distinguishing quality improvement access under the HPPs from research access requiring waiver of consent.

The initiative has fostered cross-organisational collaboration and identified opportunities to improve consistency across health networks. Bridging silos—especially between Research and Quality teams—is essential to building trust and driving shared change. Improving alignment of processes between organisations through designing and testing models for project oversight, consent, and data governance, will support a trusted and sustainable learning health system.

**Biography**

Rachel is a clinical leader and implementation practitioner with over 2 decades of experience in paediatric health care, clinical governance, and health system improvement. She currently leads initiatives to embed clinical research into health care across Victorian health services, focusing on building collaboration, capability, and shared systems for improvement and learning.
With a background in speech pathology and a passion for knowledge mobilisation, Rachel's work spans clinical innovation, research translation, and co-design of systems that support ethical, high-quality care. She has held leadership and project management roles in tertiary hospitals and research partnerships.

## Wednesday 26 November 2025

| 8:30 – 9:15 | Plenary |
|---|---|

15:40 – 16:00
*The ethics of intentional infection research*
**Professor Seema Shah**
Lurie Children's Hospital, Chicago, USA

**Abstract**
In controlled human infection (CHI) research, researchers intentionally expose people to pathogens to gain scientific insights. Although CHI research has led to key breakthroughs, it remains controversial. This talk will first provide a brief historical overview of CHI research, demonstrating how ethically problematic historical research still casts a shadow on modern studies. The talk will then argue that a lack of understanding of this research contributes to ongoing ethical controversy. It will provide an ethical framework for analysing CHI research, highlighting the importance of distinguishing the ethics of creating a new model for infecting humans from using a model that has already been shown to be safe and reliable. This distinction can do important ethical work and help calibrate the level of research ethics review needed for different kinds of CHI research. The session will close by considering lessons from the analysis of CHI research that can help advance research ethics more generally.

**Biography**
Seema is a Professor of Pediatrics at Northwestern University Medical School and the Founder's Board Professor of Medical Ethics at Lurie Children's Hospital, with a courtesy appointment at Northwestern's Pritzker School of Law. She is also the Director of Research Ethics and leads the Pediatric Research Ethics and Policy Program at Lurie Children's Hospital. Her research focuses on pediatric and global health research ethics, including on ethical and regulatory issues arising in controlled human infection studies. She has served as Chair of an NIH panel on ethical considerations in conducting Zika virus human challenge trials. She is a Hastings Center Fellow and has been inducted into the Society for Pediatric Research. Seema currently serves on the National Advisory Allergy and Infectious Disease Council for the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, as an expert advisor for the World Health Organization, and as a member of a committee for the National Academies of Science, Engineering, and Medicine.

| 9:15 – 9:55 | Clinical trials and changing times – part 1 |
|---|---|

9:15 – 9:35
*Trial design – adaptive platform trials*
**Professor Steve Webb**
Monash University

**Abstract**
Adaptive platform trials are a new type of clinical trial design that are increasingly being used. The major perceived advantage of adaptive platform trials is that they can be faster and cheaper than conventional trials. This presentation will describe the key design features of adaptive platform trials, explain the origin of efficiency gains, and implications of the design to ethical issues. The presentation will also provide an introduction to the unique terminology that is used to describe some of the design features.

**Biography**
Dr Steve Webb is an intensive care specialist, Professor of Critical Care Platform Trials at Monash University, and Group Director of Research at St John of God Health Care. He is a past Chair of the Australian Clinical Trials Alliance and a current member of the Australian Health Ethics Committee. He has experience with Bayesian adaptive platform trials and other innovative designs such as cluster cross-over trials. He has been an investigator on trials with an accumulated sample size of more than 80,000 patients, is a named investigator on more than $190million of competitive research funding, and has published more than 250 manuscripts that have been cited more than 78,000 times.

## Clinical trials and changing times – part 1

9:35 – 9:55

*Structuring your HREC for CT review / panel session (pre-recorded)*

**Sally Gordon & Cathy Stevens**
Bellberry

**Abstract**

Bellberry is a national, independent, not-for-profit organisation dedicated to providing streamlined scientific and ethical review of clinical and non-clinical research across Australia. Each year, Bellberry provides oversight of more than 40% of research conducted under a Clinical Trial Notification (CTN) scheme nationally, reviewing all types and phases of research. Established in 2004, Bellberry supports 12 National Health and Medical Research Council certified Human Research Ethics Committees (HREC) and can accommodate multiple HREC meetings each week – delivering efficient, independent, and rigorous ethical and scientific reviews.

As a not-for-profit, Bellberry reinvests surplus operational funds into the Australian medical research community, demonstrating their commitment to advancing the national research capacity. In 2024, Bellberry was honoured as the national winner of the Telstra Best of Business Award for Championing Health, recognising its leadership and sustained contribution to research advancement. Bellberry also remains the only organisation in Australia accredited with the "Gold Seal" by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) – a testament to its excellence, integrity, and commitment to ethically sound research governance.

**Biography**

Sally has worked in research ethics for over 12 years, primarily within the Bellberry Operations team in a range of roles including Research Manager. She recently transitioned into the role of Quality Manager, bringing extensive experience in the review and oversight of human research. Sally holds a degree in Psychological Science with a focus on cognitive neuroscience and has a background in nursing in the nurse in aged care sector before moving into the research ethics field.

Cathy is the Member Manager at Bellberry and is responsible for the recruitment, retention, education and support of appropriately skilled HREC members, and for managing the calendar of HREC meetings. This involves coordination of nearly 200 members throughout Australia and New Zealand and 12 committees. Cathy has an extensive background in Human Resources; she has been at Bellberry for 16 years and first became involved as a HREC member.

## 10:00 – 11:30 Privacy

10:00 – 11:30

*Privacy essentials [unrecorded session]*

**Andrea Calleia**
Helios Salinger Privacy

**Abstract**

To assess research proposals effectively, HRECs must be able to correctly apply the requirements of research exemptions under privacy laws. Join this webinar to understand how to navigate seemingly complex privacy rules, and apply them in a research context. This 1.5-hour-long webinar by leading privacy trainer Andrea Calleia, Director of Learning with Helios, offers a valuable opportunity for participants who want tips to understand how privacy compliance tests should be applied by HRECs to research proposals.

We will touch on topics such as:

- what privacy means and when it arises in the research context
- how HRECs should be thinking about privacy, and the scope of personal information
- what makes a consent valid, and when it is needed
- HRECs and the research exemption.

**Biography**
Andrea, Director of Learning with Helios, has extensive experience in the learning and development field, and has specialised in privacy training since 2003 when she managed the privacy education program for the NSW Privacy Commissioner's Office. Since joining Salinger Privacy in 2008, who recently joined Helios in 2024, Andrea has managed their e-learning privacy training program and delivers most of their face-to-face training. She has developed and delivered customised privacy training on behalf of clients including QANTAS, Sage Software, the Office of the Australian Information Commissioner, and PRAXIS Australia.

## 11:45 – 12:45 Abstract parallel session 1

11:45 – 12:00
*Healthcare quality, mystery shopping and research ethics*
**Dr Sharon Schembri**
James Cook University

**Abstract**

Mystery shopping, traditionally used in retail settings to assess service quality, has found a novel application in the Australian health care sector. This method involves trained individuals, where pseudo patients pose as real patients, to evaluate the quality, accessibility, and compliance of health care services. In Australia, this approach has been particularly prominent in community pharmacy settings, where it has been used to assess the management of non-prescription medicine requests.

A notable example is a study across 36 community pharmacies in metropolitan Sydney, where pharmacy students acted as mystery shoppers. The study aimed to determine whether repeated visits, combined with immediate feedback and coaching, could improve pharmacy performance. Results showed significant improvements in both questioning scores and the appropriateness of outcomes over time, especially when pharmacists were directly involved in the interactions.

The application of mystery shopping in health care, however, raises important ethical considerations. Unlike retail environments, healthcare involves sensitive personal information and vulnerable populations. The use of deception, even if temporary and for research purposes, can challenge the principles of informed consent and autonomy. Given research in Australia must comply with the National Statement on Ethical Conduct in Human Research, participants should be fully informed and voluntarily consent to their involvement.

In some cases, consent is obtained from health care providers in advance, as was done in the Sydney pharmacy study, to mitigate ethical concerns. Yet, this can influence behaviour and potentially skew results, highlighting the tension between methodological rigour and ethical transparency. While mystery shopping offers valuable insights into health care service delivery in Australia, its use must be carefully balanced with ethical obligations. Transparent protocols, ethical oversight, and respect for participants' rights are essential to ensure that such research contributes positively to healthcare quality without compromising ethical standards.

**Biography**
Sharon holds a PhD in Management from The University of Queensland and brings over 25 years of experience in higher education and research ethics. She has served in senior academic leadership roles in both Australia and the USA, including IRB Chair at University of Texas Rio Grande Valley. Her research focuses on consumer experience and ethical, culturally responsive methodologies. Widely published, she is committed to inclusive, community-engaged research that amplifies diverse voices and upholds the highest standards of ethical practice.

## Abstract parallel session 1

12:00 – 12:15
*Applying a translational ethics model to facilitate rigorous, high-quality, postgraduate health services research*
**Dr Robyn Taylor**[1], **Dr Claire Deakin**[1], **Dr Shayema Khorshed**[1], **Kellie Hansen**[2], **Jason Lawrence**[3], **Simon Radmore**[4 1], **Professor David Greenfield**[1]
[1] School of Population Health, University of New South Wales

[2] Western Sydney Local Health District
[3] South Western Sydney Local Health District
[4] Northern Sydney Local Health District

**Abstract**
Integrating comprehensive ethics training into postgraduate translational research programs can foster student appreciation of independent review, internalisation of a code of ethical conduct, and encourage rigorous, high-quality research. This talk present a Translational Ethics Model (TEM) for feasibly incorporating ethical review into a one-year postgraduate health management research program. It was collectively developed from experience working with a translational research course, that spans 3 Local Health Districts in New South Wales.

The TEM has 6 components: (1) relationships with health-site ethics teams, (2) professional mentorship, (3) curriculum ethics training (4) minimal-low risk projects, (5) course data collection guidelines, and (6) health-site templates for research scoping.

Relationships with health-site ethics teams are essential to support students to understand the specific ethical governance approval process adopted by their office. Ethics teams provide expert advice regarding application submission processes, can offer protocol peer review, and problem-solve any issues which surface during the review process.

Students are mentored by a professional industry sponsor to ensure student projects are aligned to strategic and operational priorities. Those sponsors are often listed as the coordinating principal investigator. They support the student to gain site access and organisational approval to conduct the study.

Ethical research values and risk levels, reflected in the National Guidelines, are taught from the first seminar and integrated into every supervision meeting. This prompts helpful discussion on how they can be operationalised in the research phases and how projects can be contained too minimal to low risk.

**Team biography**
**Dr Robyn Taylor**[1], **Dr Claire Deakin**[1], **Dr Shayema Khorshed**[1], **Kellie Hansen**[2], **Jason Lawrence**[3], **Simon Radmore** [4 1], **Professor David Greenfield**[1]

[1] School of Population Health, University of New South Wales
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[4] Northern Sydney Local Health District

The translational research collaborative is comprised of 4 UNSW academics and 3 senior NSW health practitioners. Together, they share a passion for developing future health leaders that have the skills to make evidence-based organisational improvements. Their partnership is anchored in co-managing PHCM9153 Translational Research Project, a core course in the UNSW Master of Health Leadership and Management program. Together, they support students in developing and scoping research projects, navigating ethics and site governance approvals, and disseminating findings to drive service improvement. The long-standing relationship amongst the team ensures strong alignment between academic learning and health system strategic and operational priorities.

## Abstract parallel session 1

12:15 – 12:30
*The Victorian Ethics Network: building collaboration and capacity in human research ethics*
**Dr Peter Burke**
RMIT University

**Abstract**
Established in the early 2010s, the Victorian Ethics Network (VEN) brings together administrators and professional staff from universities and other institutions across Victoria with NHMRC registered HRECs. Members of VEN are experienced and developing human research ethics professionals dedicated to supporting ethical research practices within their respective

organisations. Membership is primarily from Victorian higher education institutions but also includes other organisations without links to the higher education sector.

The network convenes regularly to address shared challenges and explore opportunities within the human research ethics landscape. Through the exchange of ideas, resources, training initiatives and mutual support, VEN fosters a collegial and resilient ethics community across the state. This presentation will provide an overview of VEN's purpose and structure and will highlight key achievements and the value the network has delivered to the Victorian human research ethics sector.

By looking at the emergence and longevity of the VEN, this presentation will also help to identify the value and importance of networks amongst professionals in human research ethics administration and the provision of support for HREC members. What lessons does the VEN provide for the broader research ethics community about the role and value of professional networks in the human research ethics space?

**Biography**

Peter is the current convenor of the Victorian Ethics Network (VEN) and has been involved in the VEN since it formed around 2010 as a network for professional staff from higher education and other institutions involved in human research ethics. When not convening VEN, he is secretary to the RMIT University HREC in Melbourne. His involvement in human research ethics stretches back to the beginning of his career in higher education research administration in the early 2000s. This presentation is the result of a joint effort and was developed by a cast of VEN members including Dr Astrid Nordmann and Dr Souheir Houssami of Swinburne and Monash University, respectively.

## Abstract parallel session 1

12:30 – 12:45

*What needs to change to ensure LGBTQ+ people are included in cancer clinical trials?*

**Celine Daignault**
The University of Sydney

**Abstract**

Ensuring that LGBTQ+ individuals have access to clinical trials is vital for scientific representativeness and upholding human rights, particularly the right to health. It's important that trials neither exclude sexuality and gender diverse people explicitly – through direct exclusion criteria – nor implicitly, using exclusionary cisnormative and heteronormative language. Cancer clinical trials collect participant demographic data, however, information regarding sexuality and gender diversity is poorly captured and reported. This project aims to understand current practices in data collection and reporting of sexuality and gender among the cancer clinical trials workforce to inform recommendations to increase LGBTQ+ participation in trials. This project is a part of the NSW LGBTQ+ Health Strategy and ongoing partnership between ACON and the Cancer Institute NSW.

The scoping review discovered that there is a paucity of data surrounding LGBTQ+ participation in cancer clinical trials in Australia, and barriers to use and collection of data for this community included a lack of LGBTQ+ focused training, clinicians forming assumptions about gender and sexuality of the presenting patients, and exclusionary language in trial eligibility and information. Six actions have been recommended, including actions that are relevant to HRECs. These include advocating for consideration of the Australian Bureau of Statistics (ABS) *Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables* in the clinical trial review process, and inclusion of the ABS Standard in the national ethics statement. Progress on recommended actions will be presented.

**Biography**

Celine Daignault is the Clinical Trials Optimisation Manager in the Clinical Trials Program at the Cancer Institute NSW. She is passionate about improving equity of access to clinical trials, and brings diverse experience in rural and urban health care in the private and public sector.

## Abstract parallel session 2

11:45 – 12:00
*Sharing clinical research results with Australian participants*
**Gudrun Wells**
CT:IQ

**Abstract**
The National Statement encourages researchers to share the results of research projects with participants and includes this as one of the elements of research. However, many participants report that they do not receive these results. This can have significant impacts on participants' wellbeing and public trust in the clinical trials enterprise.

There are valid reasons why this is the case: sites often close well before sponsors finalise lay summaries of results (assuming these get developed at all), and sponsors need sites to share results with participants. There is also no requirement to share these results in Australia, and commercial sponsors have expressed uncertainty about how these summaries interact with the Medicines Australia Code of Conduct.

Our presentation focuses on the role of HRECs in ensuring participants are provided with study results. Again, there are systematic and logistical challenges when it comes to this role. For one, HRECs often focus predominantly on approving the original application, and managing amendments, annual reports and safety incidents during the trial. This can leave limited time to also take on a burden of responsibility for overseeing the provision of study results. Additionally, researchers only rarely communicate the results of the research to HRECs, especially given the HREC approval may have completed a long time previously.

This presentation will discuss both the challenges of ensuring participants are provided with study results as well as opportunities to think creatively to ensure that HRECs have appropriate oversight of these important participant facing documents. This includes an examination of how other countries have engaged with these problems and offer suggestions for the Australian landscape.

**Biography**
Gudrun is a Senior Research Officer working with CT:IQ and Bellberry Ltd. Since taking up this role in 2023, Gudrun has been the lead on projects looking at ongoing communication with research participants and how to deliver trials more flexibly (e.g. the Beyond the Form and Flexible Trial Delivery projects), and has worked on many other efforts to improve the clinical research ecosystem in Australia, including the InFORMed template (redesigning participant consent forms) and the New Approach Methodologies thought leadership project. Before her current role, she worked as a clinical trial coordinator in a range of health conditions and worked in research governance simplifying her university's clinical research approval processes and establishing monitoring protocols. She has a BSci (Hons) from ANU.

## Abstract parallel session 2

12:00 – 12:15
*Implementation of AI assistant for training of IRB analysts: a novel educational approach*
**Chong Xue Jun Jaylynn**
NHG Health, Singapore

**Abstract**
Training new Institutional Review Board (IRB) analysts traditionally requires comprehensive study of Standard Operating Procedures (SOPs), regulations, and practical application reviews alongside experienced mentors. Current challenges include inconsistent training across different mentors, limited mentor availability during staff shortages, and the complexity of research protocols. Additionally, the loss of institutional knowledge during staff turnover highlights the need for robust knowledge retention systems. The objectives of this project are to explore the use of two Artificial Intelligence (AI) assistants designed to enhance IRB analyst training for ethics review of research involving medical records. This pilot project aims to ensure consistent knowledge retention and application, reduce dependency on mentors, and enable independent training opportunities.

Key benefits identified from the qualitative survey include a standardised review and query approach, immediate access to a knowledge database, reduced dependency on mentors, and support for self-paced learning. The AI tool was most effective in situations where immediate answers to knowledge-based questions were needed. Whilst there are significant benefits to using the AI assistants, the survey responses revealed that the AI tool should complement rather than replace traditional mentee and mentor training. This is particularly true for complex reviews requiring human experience and professional judgement, as well as the human emotional intelligence and empathy needed when coaching new staff.

Preliminary results suggest promise for AI-assisted trainings, enabling faster and more consistent training whilst maximising new staff independence. However, AI assistance works best as a supplement to traditional mentoring rather than a replacement. Users noted that complex cases still required human guidance, particularly those involving nuanced ethical considerations or situations requiring interpersonal skills when providing feedback to researchers. Further evaluation with larger cohorts and longer-term assessment would be needed to fully understand the impact on training effectiveness and staff competency development.

**Biography**
Chong Xue Jun Jaylynn is the Assistant Manager of the Research Quality Management sub-unit under the Office of Human Research Protection Programme (OHRPP), Group Research & Innovation, NHG Health. She is responsible for conducting research audits and monitoring to ensure ethical and regulatory compliance and leads AI adoption and change management initiatives within OHRPP to enhance research oversight and efficiency.

## Abstract parallel session 2

12:15 – 12:30
*Redesigning Queensland Health's approach to translational innovation – shining a light on improvement, innovation, evaluation and audit activities*
**Beth Wray**
Clinical Excellence Queensland

**Abstract**
Under the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2025), two parallel pathways have always existed: HREC review and exemption. The dominance of the HREC pathway has created delays to projects intended to make practical improvements to the health system, and a culture that leaves improvement, innovation, evaluation and audit activities under-supported at a time when translational innovation demands proportionate, streamlined approaches. Priorities 4 and 5 of the Health Translation Queensland Action Plan call for translation of research into practice (TRIP) and for harmonisation and streamlining of approval processes. Yet, current models risk constraining the very activities that enable evidence-informed change at pace.

A recent project examining how improvement, innovation, evaluation, and audit activities are captured, registered, reported, and shared statewide identified that these projects often sit within HREC pathways inappropriately. Extensive stakeholder engagement confirmed the need to design a robust, scalable exemption pathway to address these systemic challenges. Queensland Health is responding by establishing proportionate, streamlined approval pathways consistent with the NHMRC National Statement, yet responsive to contemporary innovation needs. This initiative is building the infrastructure for translational innovation, ensuring that improvement, innovation, evaluation and audit activities are legitimised as the enabling mechanism to drive TRIP and connect research outputs with real-world impact. By redefining governance boundaries and challenging entrenched assumptions, we create the conditions for thought leadership, increased scholarly outputs, and faster translation of improvement and innovation into practice.

**Biography**
Beth is a nursing leader committed to driving evidence-based change and transformation across the health care system. Through the Queensland Innovation Living Lab (QuILL), she is currently supporting strategic initiatives aimed at enabling and strengthening collaboration, knowledge

exchange, and shared learning across the Queensland Health ecosystem. Her work focuses on accelerating the adoption, scale, spread, and sustainability of successful initiatives, while reducing barriers such as duplication of effort, project abandonment, and delays in implementation. Beth is passionate about fostering a culture that invests in, and values, a diverse range of activities that seek to inform change and improve health outcomes, including quality improvement, evaluation and innovation.

## Abstract parallel session 2

12:30 – 12:45

*Lived experience people in research design and conduct*

**Lisa Treverrow**
Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS)

**Abstract**

The session will highlight the importance of Indigenous-led research and advocate for ethical, respectful, and reciprocal research practices. Central to this is the recognition and protection of Indigenous Data Sovereignty (IDS) and Indigenous Cultural and Intellectual Property (ICIP). Research involving Indigenous peoples must be guided by genuine partnerships respecting the primacy of the right to self-determination and ensuring that any knowledge generated or outcomes directly benefit the communities involved. The AIATSIS Code serves as a foundational research framework to support researchers for engaging in culturally safe, community-led research that upholds these principles.

When research is Indigenous led and controlled, this becomes a tool for empowerment as opposed to exploitation. Indigenous-led research ensures relevance, cultural integrity, and positive social impact. This safeguards the rights and interests of Indigenous peoples by emphasising ethical standards, collaborative methodologies, and appropriate governance of knowledge systems. AIATSIS is playing a pivotal role in shifting research paradigms by providing clear ethical guidelines and promoting a model of research that is *for* communities, *by* communities.

**Biography**

Lisa is a non-Indigenous woman born and raised on the land of the Ngunnawal People (Canberra). Lisa has worked across a range of Australian Government Departments from Intellectual Property to the Disability Sector. Throughout this time Lisa came to learn of the expanse of injustices that the colonisation of Australia has imposed on the Aboriginal and Torres Strait Islander peoples and this inspired a passion to genuinely makes a difference for Aboriginal and Torres Strait Islander Peoples. Lisa has worked as an Executive Director with the Australian Indigenous Doctors Association. She commenced work with AIATSIS in early 2024 and is the Assistant Director, AIATSIS Ethics and Research Governance (A/g).

## Abstract parallel session 2

12:45 – 13:00

*Research adequacy, AI, and the creation of mHealth Apps*

**Dr Dana Wensley**
University of Auckland

**Abstract**

Since 2020 there has been an increase in the development and usage of mHealth (mobile health) apps. It is projected that this market will increase in the next decade, changing the face of health care with the potential to reshape tracking of illness, monitoring of chronic conditions, providing real-time readings of basic metabolic functions, and providing mobile access for patients to access medical history and lab results.

The talk will focus on 2 areas of ethical concern. First, the issue of research adequacy is considered. The session will explore how research ethics committees discharge their responsibility to ensure research adequacy in the study design. This covers issues of insufficient datasets, biased or inaccurate information being used to train the app, and the extent to which committees ensure adequate engagement has occurred with those who have lived experience of

the condition or chronic disease. Secondly, the session will explore the manner in which research ethics committees balance the competing goals of respect for privacy with the public good when making decisions about access to datasets. The presentation then asks if we are doing enough to ensure that public data used without consent to train mHealth Apps is used in a manner that will deliver equitable results, and will not exacerbate existing inequalities.

**Biography**

Dana has been appointed as the new Head of Research Ethics at University of Auckland. Dana started her career as a registered nurse at Greenlane Hospital and went on to complete an LLB (Hons, University of Auckland), an MA in Medical Law and Ethics and a PhD in Medical Law and Ethics at King's College London after being inspired by the events of the Cartwright Inquiry. Following her PhD, Dana worked as a Senior Research Fellow with the Human Genome Project at the University of Otago and subsequently held a series of governance and expert advisory roles at the local and national level. She has received Ministerial appointments in ethics, including serving for 6 years on the National Ethics Advisory Committee where she was a key contributor to the National Ethical Standards for Health and Disability Research and Quality Improvement and as the ethics expert on the End of Life Review Committee.

## 13:00 – 14:30 Psychedelic drugs in research

13:00 – 13:30

*ACT HREC PAT authorised prescriber update and issues*

**Professor Nick Glasgow**

Australian National University

**Abstract**

ACT HREC decided to accept applications from psychiatrists seeking HREC approval of applications to be Authorised Prescribers of MDMA and/or psilocybin in 2023. The presentation will summarise ACT HREC experience to date in terms of numbers of applications received, location of applicants, and emergent issues the ACT HREC has grappled with. It will summarise the current approach taken by ACT HREC in response to this experience.

**Biography**

Nicholas was appointed Chair of the ACT HREC in 2025. He is a retired general practitioner and palliative medicine specialist and was appointed Emeritus Professor at the Australian National University (ANU) in March 2018. He served in several roles at the ANU including as Dean, Medicine and Health Sciences, and Dean, Medical School; and as Professor and Director of the Australian Primary Health Care Research Institute. He was appointed to a 2-year term as Chair of the Academic Board of the ANU in 2014 and is a past President of Medical Deans Australia and New Zealand.

He graduated Bachelor of Medicine, Bachelor of Surgery from the University of Auckland in 1981, and obtained his doctorate from the University of Auckland in 1999. In 2009, his international contributions to the discipline of general practice were recognised with the award of Distinguished Fellow by the Royal New Zealand College of General Practitioners. In 2017 he received an honorary Doctor of Medicine from the International Medical University in Malaysia in recognition of his leadership in medicine.

His research interests include asthma and respiratory health, chronic disease care, end of life care, and health system research including health workforce research. He has a long-standing interest in the scholarship of teaching and learning in medicine and the application of that scholarship to medical education programs. He undertakes accreditation roles for the Australian Medical Council (AMC) including accreditation of medical school programs and specialist college programs. He has been involved with the AMC led National Framework for Prevocational Medical Training Review which designed and planned implementation of a new program for PGY 1 and PGY 2 education in Australia.

## Psychedelic drugs in research

13:30 – 14:00

*A new era for psychedelic-assisted therapy trials: safety, ethics, and progress*

**Professor Susan Rossell & Associate Professor Vanessa Beesley**
QIMR Berghofer

**Biography**
Vanessa is a behavioural scientist and team head of the Psychedelic Medicine and Supportive Care Laboratory at QIMR Berghofer. She led a psilocybin-assisted psychotherapy trial for prolonged grief and is the coordinating principal investigator of a new MDMA-assisted therapy for climate-related PTSD. With over 2 decades in psycho-oncology, Vanessa has also led counselling and exercise trials, published more than 70 scientific articles, advised government, and organises the Northern Australia Psychedelic Science (NAPS) conference.

## Psychedelic drugs in research

14:00 – 14:30
*Treatment using psychedelics – practical and ethical challenges and solutions*
**Dr Franklin King**
Center for the Neuroscience of Psychedelics, Massachusetts General Hospital

**Biography**
**Franklin serves as the Director of Training and Education at the** Massachusetts General Hospital (MHG) Center for the Neuroscience of Psychedelics and holds a faculty position as a Clinical Instructor at Harvard Medical School. His primary clinical and research focus is on the application of psychedelic-assisted psychotherapy for the treatment of persistent psychiatric conditions, such as depression and anxiety disorders. In addition to his research and clinical work, he is actively involved in the education and supervision of psychiatric residents and fellows at MHG. He also maintains a clinical practice as a staff psychiatrist at the Center for Anxiety and Traumatic Stress Disorders and provides care on the Acute Psychiatry Service in the Emergency Department.

## 14:40 – 15:35 Clinical trials and changing times – part 2

14:40 – 15:05
*Charter for healthy volunteer trials*
**François Bompart**
VOLRETHICS Association, France

**Abstract**
Healthy volunteers (HVs) who participate in research play a significant role in the advancement of science and medicine. Yet, they are often a 'blind spot' in biomedical research ethics. Most laws and regulations to protect research participants are focused on patients taking part in trials, and only a handful of countries have specific provisions for the protection of HVs. This should be a cause of concern since HVs' involvement in research significantly differs from patients' on 3 main accounts. First, unlike patients, HVs cannot expect direct medical benefit from participating and, therefore, have a different benefit–risk balance. Second, HVs participate in studies with much more stringent rules than patients that might impinge on their wellbeing. Third, the prospect of financial compensation, usually the decisive factor in agreeing to participate, exposes HVs to the risk of being exploited when they are in situations of vulnerability. This presentation will outline the key features of the first Global Ethics Charter for the Protection of Healthy Volunteers in Clinical Trials issued in 2024 by the international VOLRETHICS initiative. This Global Charter is intended to raise awareness about the specificities of HVs in research and foster debates on how each country and each REC can ensure adherence to the best scientific and ethical standards for all research participants, patients and HVs alike.

**Biography**
François is a member of the French National Institute for Health and Medical Research (INSERM)'s Ethics Committee and the former Chair of the Access Committee of the Drugs for Neglected Diseases initiative (DNDi), a non-profit organisation based in Geneva (Switzerland). He worked for over 25 years in anti-infective medicines and vaccines, with a focus on emerging and developing countries, mostly within the Sanofi pharmaceutical group. His main fields of interest are related to infectious diseases, access to care in resource-limited countries, as well

as ethical issues in clinical research.

His specific interest in ethical issues related to healthy volunteers started with being a healthy volunteer himself in the 1980s, then an investigator and, later, a sponsor of many Phase I studies. He worked with the INSERM Ethics Committee to initiate the work that led to the VolREthics initiative's creation in 2022. The VolREthics initiative aims at protecting healthy volunteers in biomedical research from harm and from exploitation everywhere in the world. The VOLRETHICS Association was created in 2025 to provide a formal framework for the initiative, with François Bompart as its first President. He received his MD from the University of Angers (France) and trained in Clinical Pharmacology at University College London (UK) and Hôpital Cochin in Paris (France).

## Clinical trials and changing times – part 2

15:05 – 15:20

*Ethics & governance review of adaptive platform trials: practical guidance for HRECs and research officers*

**Sophie Gatenby**
Royal Children's Hospital Melbourne

**Abstract**

Adaptive platform trials (APTs) represent a powerful and increasingly used model for evaluation multiple interventions within a single, flexible trial infrastructure. However, their novel design elements pose distinct ethical and governance challenges – including issues of informed consent, clinical equipoise, ongoing adaptations and oversight. This session will provide targeted guidance on how HRECs and research ethics and governance officers can effectively review APTs with a focus on supporting dialogue between research office and researcher.

**Biography**

Sophie has worked in the Research Ethics and Governance Office at the Royal Children's Hospital Melbourne for over 10 years and has provided guidance for many of the LifeCourse projects over this time. Over this decade there have been many changes in the guidance and legislation that govern the use of secondary data in addition to a shift in societal expectation on how information is used. Sophie is passionate about using her expertise in research ethics to help support researchers on campus. She completed her B/Science Communication at ANU in 2009 followed by her MPH at the University of Newcastle.

## Clinical trials and changing times – part 2

15:20 – 15:35

*Facilitators and barriers to the clinical trial recruitment of older people: a qualitative study*

**Sue Markham**
University of Sydney

**Abstract**

Older people are consistently under-represented or excluded from clinical trials investigating treatments for conditions that commonly affect them. The main objective of this project was to explore how accepted, socially constructed 'truths' about ageing and older people inform key stakeholders' discourses, beliefs and assumptions and subsequently affect clinical trial recruitment practices. Key stakeholders include researchers, human ethics committee members and older people with and without trial experience. The project also involved a review of Australian and international clinical trial guidance relating to the inclusion of older participants and analyses of Australian clinical trial protocols to assess criteria that may exclude older participants.

Findings revealed that many stakeholders had absorbed common age stereotypes which influenced their assumptions and expectations about older people as clinical trial participants. There was a level of disinterest and lack of engagement with the issue of under-representation among some general researchers and ethics committee members. There was also a lack of awareness and focus on the concept of injustice in excluding older people from clinical trials and the ethical implications of doing so. Researchers who work closely with older people were more

aware of and largely challenged negative assumptions and beliefs about older people through recruitment approaches built on inclusivity and purposeful, targeted actions. Most older people constructed an identity that was not defined by age or age stereotypes. They wanted to contribute to the greater good and advance medical knowledge through trial participation, with many speaking against the homogenisation of older people and the inequitable exclusion of older trial participants.

Analysis of clinical trial guidelines revealed that Australia is out of step with similar countries in failing to specifically address the issue of older people's under-representation in clinical trials. Analysis of registered Australian trial protocols showed the presence of upper age limits and exclusion criteria that are likely to disproportionately exclude older people from trial participation. These results may facilitate recognition of the impact of age stereotypes on older people as prospective clinical trial participants and lead to greater awareness of the need to improve the representation of older people in research.

**Biography**
Sue has just completed a PhD examining the facilitators and barriers to the recruitment of older clinical trial participants, particularly the impact of sociocultural stereotypes and attitudes towards older people. Sue completed a Master's degree in 2020, which involved a systematic review examining ageism and age-based decision-making among healthcare professionals and researchers. Sue worked for over 25 years as a medical writer, developing medical education projects for healthcare professionals, and was a clinical physiotherapist for 10 years. She has a special interest in older people's accessibility to health and medical research, and the importance of including older people in clinical trials.

## 15:40 – 16:40 HREC member panel discussion

*Role and challenges for HREC members*

**Panellists**
**Alison Bradshaw**
Central Adelaide Local Health network
**Lucy Lopez**
The University of Queensland HREC
**David Luttrell**
RPA HREC
**Geoff Vass**
Women's and Children's Health Network HREC

## Thursday 27 November 2025

### 8:00 – 9:20 Regulation & legislation

8:00 – 8:20

*Building a new framework for research tissue regulation in Australia: the Australian Law Reform Commission's proposals for reform*

**Dr Meaghan Toews**
Australian Law Reform Commission

**Abstract**

The Australian Law Reform Commission (ALRC) is currently conducting an inquiry into the law of human tissue. A key area of focus for this inquiry is the donation and use of tissue for research. Prior to the session, a Discussion Paper will be published that puts forward initial ideas for reforming how human tissue is regulated in Australia (available at www.alrc.gov.au). This session will focus on the Discussion Paper proposals that are specific to the research context. Topics of discussion will include the regulation of tissue donation and research using (i) tissue from living and deceased participants; (ii) tissue from those with decision-making capacity and those without; and (iii) tissue that was specifically donated for research and tissue that was originally obtained for a non-research purpose. This session will provide an opportunity for robust and thoughtful discussion of the ALRC's proposals, and a unique opportunity for engagement between the HREC community and the ALRC.

**Biography**

Maeghan is a full-time Commissioner with the Australian Law Reform Commission, appointed to lead the ALRC's Review of Human Tissue Laws alongside ALRC President, the Hon Justice Mordecai Bromberg. She is a legal academic specialising in the law pertaining to human biomaterials. Her work spans both research and therapeutic uses for human tissue, examining legal and ethical regulatory frameworks. She has contributed to interdisciplinary collaborations on projects related to personalised medicine, genomics, stem cells, prenatal testing, biobanking, and transplantation, and led the development of international legislative consensus guidelines for the donation of human tissue.

### Regulation & legislation

8:20 – 8:35

*Update: quality standards and accreditation scheme for HRECs and their host institutions*

**Michael Swarbrick**
Australian Government Department of Health, Disability and Ageing

**Abstract**

The Australian Government remains committed to investing in health and medical research and recognises the critical role research plays in contributing to our world-class health system.

The Department of Health, Disability and Ageing (the Department) is leading national reforms to improve the operating environment for health and medical research, including clinical trials, via the enduring Inter-Governmental Policy Reform Group (IGPRG). IGPRG is implementing a nationally harmonised and predictable eco-system to promote Australia as a preferred destination for health and medical research and places clinical trials at the forefront of a sector-wide research investment and innovation drive. A key initiative under these reforms is the development of Quality Standards and an accreditation scheme for HRECs and their host institutions.

Accreditation provides an opportunity to improve consistency, efficiency and accountability in the ethics review process, to foster trust among HRECs and institutions, and to promote mutual acceptance of ethics reviews. This will ensure that HRECs and their host institutions operate in a manner commensurate with the levels of excellence expected in Australia.

The draft Quality Standards were co-designed with all jurisdictions via the IGPRG. They consist of 3 Standards (2 for institutions and one for HRECs). Each Standard has specific actions that

need to be met, suggested strategies an institution/HREC could implement to meet the Standard, and examples of evidence to substantiate that the Standard has been met.

In March/April 2025, the Department conducted public consultations on the draft Quality Standards and options for the proposed accreditation scheme.

**Biography**
Michael is an Assistant Director in the Clinical Policy Section of the Australian Government Department of Health, Disability and Aging. Michael is currently collaborating with state/territory governments and government agencies to develop quality standards and an accreditation scheme for HRECs and their host institutions. This project is one of the key upcoming reforms to Australia's health and medical research sector.
Prior to joining the department, Michael was a biomedical researcher for 20 years, working in the field of aging-related diseases, such as type 2 diabetes, obesity, and osteoporosis. He conducted research at the University of Western Australia, University of California (San Francisco and Davis), and the Garvan, Westmead and ANZAC Institutes in Sydney, Australia.

## Regulation & legislation

8:35 – 8:50
*TGA update on psychedelic assisted therapy*
**Professor Robyn Langham**
Therapeutic Goods Administration

**Abstract**
This presentation provides an overview of the Therapeutic Goods Administration's (TGA) current regulatory position and recent developments relating to psychedelic-assisted therapy in Australia. It will cover the framework for prescribing under the Authorised Prescriber Scheme and updates from the recent TGA Targeted external consultation paper, *Review of Authorised Prescriber Scheme to allow access to 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybine for use with psychotherapy in mental health conditions.* The session will also highlight emerging trends and the role of HRECs in supporting safe access.

**Biography**
Robyn is the Chief Medical Adviser of the Therapeutic Goods Administration in Australia. She is a nephrologist and clinician researcher, focusing on drug development of novel anti-inflammatory and anti-fibrotic agents. Professor Langham is also a director of the Australian Medical Council and chairs the Human Research and Ethics Committee at the Royal Children's Hospital in Melbourne.

## Regulation & legislation

8:50 – 9:05
*TGA principles to practice: governance, regulation and compliance for AI-enabled human research*
**Bridgette Basnayt**
University of Southern Queensland

**Abstract**
Industry 5.0 reframes the trajectory of digital transformation by positioning artificial intelligence (AI) as a tool humans collaborate with, rather than a simple replacement of tasks. To achieve the aim of ethical human-AI collaboration, research governance must have a guiding framework shaping how AI is designed, governed, and translated into responsible impact.

This technical expansion has not been matched with equivalent investment in governance, regulation, and compliance. The resulting imbalance risks advancing capacity beyond the voluntary guardrails intended to ensure trust and accountability. The risks are visible in the rise of shadow AI, the unsanctioned use of accessible AI tools outside approved governance frameworks. Usually deployed with good intentions, shadow AI bypasses oversight, informed consent, and accountability, exposing research to systemic vulnerabilities. Such practices illustrate the gap between technical capability and ethical readiness, and the need for stronger

frameworks that anticipate and not just react to AI adoption. Comparative perspectives reveal different approaches to this challenge.

Australia's National Statement on Ethical Conduct in Human Research (2025) adopts a technology-neutral stance, emphasising principles such as privacy, fairness, and the prevention of systemic harms. In contrast, New Zealand's National Ethical Standards for Health and Disability Research and Quality Improvement (2019) offers an important model at a time before the current large language models wave. It explicitly defines AI, embeds Māori Data Sovereignty, and requires explainability and oversight throughout the AI lifecycle. This culturally grounded approach demonstrates how ethics can be embedded proactively.

The future of responsible AI research in Australia and New Zealand will depend on bridging the gap between innovation and governance. Governance-ready research design, co-designed with communities, and aligned with intellectual property and provenance strategies, will be essential to translate AI from research into practice without compromising integrity, sovereignty, or trust.

**Biography**

Bridgette integrates expertise in operational excellence, psychology, and AI governance to promote ethical foundations of health systems and emerging mental health technologies. She holds a Bachelor of Commerce and is completing a Bachelor of Psychology at the University of Southern Queensland. Bridgette is also a 2025 Centre for Health Research Scholar with the Momentum Hub digital mental health program for children and young people. Her research focuses on governance, regulation, and compliance frameworks for AI-enabled interventions. An aspiring Neuropsychologist, Bridgette's research also examines culturally responsive and evidence-based approaches to wellbeing, resilience, spirituality, and youth justice. She is deeply engaged in her community, and balances academic and professional pursuits with raising two young children, who inspire her commitment to inclusive, ethical, and human-centred research and innovation.

## Regulation & legislation

9:05 – 9:20
*Chair discussion & question time*
**Adjunct Professor Gordon McGurk**
Southern Cross University

## 9:30 – 11:15 Operationalisation & quality assurance

9:30 – 9:50
*The canReview Project*
**Susan Marlin**
Clinical Trials Ontario

**Abstract**

CanReview is a new initiative in Canada, designed to achieve a single research ethics review for multi-site clinical trial or health research studies. Following a public Request for Proposals issued by the Accelerating Clinical Trials (ACT) Consortium, and a review process including Canadian and international experts, the CanReview Collaboration was selected to develop and launch a transparent, single research ethics review process with strict timelines. As CanReview is about to launch across Canada, this presentation will provide an overview of CanReview's progress to date and the challenges and opportunities in implementing a single review across provincial borders in Canada.

**Biography**

Susan is a trusted leader in Canada's research ethics and clinical trials community. As the President and CEO of Clinical Trials Ontario (CTO), she collaborates to strengthen the clinical trials environment while maintaining the highest ethical and quality standards. Susan was foundational in establishing CTO's streamlined research ethics review system to enable a single review for multi-site clinical trials and health research studies in Ontario which now has more than 11,000 users, 160 participating sites, 300 pharmaceutical and medical device companies, and 20 qualified research ethics boards.

Building on her record of uniting partners to streamline clinical trials, Susan is advancing key projects across Canada. She is the nominated principal investigator for the Canada-wide CHEER project, supported by the Canadian Institutes of Health Research (CIHR) to streamline ethics reviews for child health research. She is also the nominated principal applicant for the CanReview collaboration to establish a pan-Canadian single research ethics review system, supported by the CIHR-funded Accelerating Clinical Trials (ACT) Consortium.

Prior to CTO, Susan served as the Associate Vice-Principal at Queen's University, and worked with Canadian Cancer Trials Group to coordinate clinical trials and lead the development and implementation of the Ethics and Regulatory Office. Susan has served as President of the Canadian Association of Research Ethics Boards, and as a member of the CIHR Research Integrity Committee, the Ontario Cancer Research Ethics Board, and the Tri-Agency Panel on the Responsible Conduct of Research. Susan sits on the Board of Directors and Executive Committee of Life Sciences Ontario. She serves on the Operations Committee for the ACT Consortium and is on the Management Team for the Ontario Strategy for Patient-Oriented Research Support Unit. She is an Adjunct Lecturer at Queen's University in Kingston, Ontario and received the Queen Elizabeth II Diamond Jubilee Medal in 2012 for her contributions to Military and Veterans Health Research.

## Operationalisation & quality assurance

9:50 – 10:10

*Research our way: exploring the ethics governance experiences and preferences of Aboriginal and Torres Strait Islander community controlled health organisations and HRECs of Queensland*

**Greg Pratt**
Central Queensland University, QAIHC

**Abstract**
This talk will provide a background to, and describing methods, results and recommendations arising from the Research Our Way: Human Research Ethics Governance by First Nations for Queensland Communities project. Reflecting on findings arising from a series of surveys and yarning circles with 1) HRECs and 2) Aboriginal and Torres Strait Islander community controlled health organisations (ATSICCHOs) in Queensland. The talk will also describe needs and preferences with respect to ethics governance of research involving, of relevance to, and/or led by Aboriginal and/or Torres Strait Islander people and peoples in Queensland.

**Biography**
See page 14

## Operationalisation & quality assurance

10:10 – 10:30

*Beyond tokenism: recruiting for and sustaining equitable representation on a Northern Territory Human Research Ethics Committee*

**Hayley Germaine**
Charles Darwin University

**Abstract**
The Northern Territory spans approximately one sixth of Australia's landmass and yet is home to just 1% of the population, of whom 26.3% are First Nations peoples. As a result, approximately 45% of applications submitted to the CDU-HREC for review are related to First Nations research. This presentation addresses the main challenges faced by HRECs in recruiting and sustaining equitable representation. Having viable representation that genuinely enhances and respects First Nations voices in the review process is an ongoing task, and one that CDU continues to try to address. The talk focuses on general committee membership, how to ensure culturally safe reviews of ethics applications involving First Nations research, and more recently implemented changes following an external review of the CDU HREC in 2024.

In early 2025, the CDU-HREC introduced a First Nations sub-committee to create a flexible and culturally safe space for increased First Nations committee representation. The sub-committee

convenes prior to the respective HREC meeting, at a time and in a setting that suits its members. The sub-committee reviews all First Nations projects submitted for HREC review and provides recommendations and feedback to the committee for consideration. Members of the First Nations sub-committee are inducted as HREC members, with some attending both meetings. Underlying all of this is the commitment to move beyond tokenism.

**Biography**

Hayley studied law at Monash University (1996–2000), after which she began diving with Great White sharks in South Australia, where she developed a passion for research. With a family of research nurses, her passion for research ethics and integrity expanded. She has over 8 years experience coordinating and managing research ethics committees and began in human research ethics and governance at Royal Melbourne Hospital. For the past 4 years at Charles Darwin University (CDU), she had the privilege of coordinating both the Human Research Ethics and Animal Ethics Committees. Recently the ethics team has expanded, and Hayley now coordinates the HREC and Research Integrity for CDU.
In September 2025, the CDU ethics team was one of two recipients to be awarded the RMIT Paul Taylor Award through ARMS, which recognises and celebrates excellence in research and innovation support.

## Operationalisation & quality assurance

10:30 – 10:45

*STILETTO: SupporTIng quaLity EThics applications & Timely respOnses*

**Dr Sarah Moberley**
Hunter New England Local Health District

**Abstract**

Concerns about the timeliness of ethical review and approval processes have been a continual issue in the academic community. Researchers have reported significant delays, which can impede the progress of important studies that may impact on improvements in health care delivery. This talk presents the outcomes of a project aimed at improving the quality of ethics applications and improved procedures for clearly communicating reviewers request for clarification for human research ethical review. This project demonstrated the feasibility of improved support to researchers prior to and during the ethical review process. The HREC has enjoyed higher quality applications that allow for discussion on critical ethical matters.

**Biography**

Sarah is the District Manager of Research Ethics for Hunter New England Local Health District. Sarah leads a team to support academics and clinicians ensure their research is compliant with relevant guidelines and laws. Sarah has a background in nursing, international humanitarian relief and has conducted large scale operational research and clinical trials prior to moving into the role of ethics management. Winner of the NSW Health Research Administration Leadership and Innovation Award 2 years in a row, Sarah will speak about a project that greatly improved the efficiency and timeliness of reviewing and processing ethics applications.

## Operationalisation & quality assurance

10:45 – 11:00

*Data sharing for secondary research in Australia: results from a Shared Ethical Debate (ShED) exercise*

**Dr Rebekah McWhirter**
Australian National University

**Abstract**

Australian HRECs are entrusted with authorising waivers of consent for the use of research data for secondary research. In making this decision, HRECs are required to apply criteria under national research ethics guidelines and privacy laws, including that:

- the research benefits outweigh the risks
- seeking reconsent would be impracticable
- participants would likely have consented if they had been asked, and

- sufficient protections for participant privacy and confidentiality are in place.

Through the inaugural Australian Shared Ethical Debate (ShED) exercise, it was assessed how HRECs are interpreting requirements for waivers of consent for the secondary use of clinical trial data. The exercise uncovered widespread divergence among HRECs. This included different understandings of:

- the role of HRECs in reviewing secondary data research applications
- whether the data being shared should be considered deidentified, and
- thresholds for 'impracticability' of seeking reconsent.

This presentation explores the implications of these differences, and identifies some key ways that HRECs and researchers can be supported to meet the requirements of privacy legislation and the expectations of the broader community.

**Biography**
Rebekah is Senior Lecturer and Director of Education at the Australian National University's School of Law. Her work focuses on the governance of research ethics, and ethical, legal and social implications of genomics.

## Operationalisation & quality assurance

11:00 – 11:15
*Redefining the boundaries: research, quality activities and clinical registries*
**David O'Halloran**
Department of Health Tasmania

**Abstract**
The line between research and non-research activities – quality improvement (QI), quality assurance (QA), evaluation, and clinical quality registries (CQRs) – has always been blurred. For many years, the shorthand rule of thumb was simple: "If you want to publish, it must be research". This rule pushed countless QI projects and audits into research ethics pathways, often unnecessarily. The result was clinician fatigue, disengagement, and over-engineered projects that missed their primary purpose.

We now recognise that publication is not the test. The real distinctions lie in purpose, design, and risk. Research is hypothesis-driven and methodologically bounded. By contrast, QI focuses on local service improvement through iterative cycles; QA measures compliance against benchmarks; evaluation assesses effectiveness and value; and CQRs provide ongoing benchmarking and feedback at a system level. Each has its own logic, but all raise ethical considerations.

For HRECs, this shifting boundary poses practical challenges. Applying a research paradigm to QI, evaluation, or registries can be disproportionate and burdensome. Yet leaving these activities outside review risks overlooking issues of consent, privacy, transparency, and participant trust. The task is not to erase the boundary, but to redraw it in ways that are proportionate, principled, and clear.

This presentation will map current thinking on these distinctions and highlight the risks of misclassification. It will draw on the Tasmanian experience, where practical responses are trialled: functional classification tools that help distinguish research from other activities; proportional review mechanisms such as checklists and panels; and contractual agreements that embed governance in the health system rather than in research oversight alone.

**Biography**
David is a Health Research Officer with the Tasmanian Department of Health, an occupational therapist by background who has also worked extensively in labour market policy, and now focuses on research governance, workforce development, and ethics in health care.

## Community-minded research

11:30 – 11:50
*Community-based participatory research (CBPR)*

**Associate Professor Adam Becker**
Northwestern University Feinberg School of Medicine

**Abstract**
Community-based participatory research (CBPR) involves partnerships among community-based individuals and organisations and researchers in academic institutions. CBPR prioritises the equitable engagement of community partners in all aspects of research, from conceptualisation to implementation and dissemination. Institutional entities charged with oversight of human rights protections (e.g. Institutional Review Boards or IRBs in the US, Research Ethics Committees outside of the US) prioritise, in part, adherence to established guidelines for the ethical treatment of individuals who are recruited or agree to participate in research. These 2 missions are not antithetical.

However, the notion of partners outside of academic institutions, where IRBs are primarily located, being actively engaged in the development and conduct of research can raise concerns among reviewers that sometimes result in obstacles to this approach. Additionally, community partners may feel that IRBs (a) don't go far enough by not considering the ethical treatment of communities (beyond the individuals within them) and (b) replicate the power imbalances between communities and 'the Academy' that gave rise to the development of CBPR in the first place.

This presentation will cover the key principles of CBPR, describe specific examples of tensions that arise between community and academic institutions when considering human subjects protections, and point to solutions that can address these tensions.

**Biography**
Adam is Associate Professor of Pediatrics at the Northwestern University Feinberg School of Medicine and Scientific Lead for evaluation, qualitative, and community-engaged research with the Smith Child Health Catalyst at the Stanley Manne Children's Research Institute of Chicago.

He received his Master of Public Health in 1994 and his Ph.D. in 1999, both in Health Behavior and Health Education from the University of Michigan School of Public Health. He has extensive training and experience in the practice of community-based participatory research (CBPR). He has been teaching courses in CBPR and community-engaged research since 1998 and has written several book chapters and articles on this approach to examining and addressing public health problems. Some of the issues to which Adam has applied this methodology include the impact of stressful community conditions on the health of women raising children, youth violence prevention, and the impact of the social and physical environment on physical activity.

He teaches in the MPH program at Northwestern University (NU). Prior to coming to Smith Child Health in 2006 and joining the NU faculty in 2012, he was the Director of Evaluation and Research at the Louisiana Public Health Institute and was a member of the faculty for 6 years at Tulane University's School of Public Health and Tropical Medicine, both in New Orleans.

## Community-minded research

11:50 – 12: 10
*Pre-ethics: Relational groundwork for ethical encounters [unrecorded session]*
**Sebastian J. Lowe**
Aarhus University, James Cook University

**Abstract**
'Pre-ethics' refers to the period of engagement with a community before any formal research ethics process takes place. It is a deliberate practice of slow, careful connection – creating spaces where trust is built, ideas are co-formed, and knowledge is carried forward together. Informed by Kaupapa Māori Research principles, and shaped by insights from Sebastian's Māori and non-Māori colleagues in Aotearoa New Zealand, his PhD work explores 'pre-ethics' as a response to colonisation's enduring legacies and a challenge to conventional research timelines. Drawing on co-creativity, sensory practice, ethical listening, and compositional methodologies, this session explores how 'pre-ethics' might cultivate an 'ethical

sensibility' rooted first in our encounters as humans, then as researchers. In a time of increasing social fragmentation, Seb is interested in asking: How might expression, interpretation, and connection re-energise our ethical codes? And, how might attuning to the 'relational tone' of our interactions open the way for research that is not only methodologically sound, but profoundly collaborative?

**Biography**

Sebastian (Tangata Tiriti) is an anthropologist from Aotearoa New Zealand with an enduring interest in sound worlds. He is currently completing his PhD in anthropology at Aarhus University (Denmark) and James Cook University (Australia).

## Community-minded research

12: 10 – 12:25

*Ethical gaps in the inclusion of people with dementia in self-advocacy: beyond research protocols*

**Kate Swaffer**
University of South Australia

**Abstract**

This presentation explores the ethical dimensions of including people living with dementia (PLWD) in research and self-advocacy, with a specific focus on the absence of ethical protocols governing their non-research-based involvement. In 2019, there were an estimated 57 million PLWD globally, and 10 million new cases annually. Historically, PLWD were excluded from direct participation in research due to assumptions of their perceived incapacity to consent, understand, or contribute meaningfully, stemming from biomedical framings that position dementia as a condition of decline and incapacity. However, recognising dementia as a major cause of disability and aligning with the Convention on the Rights of Persons with Disabilities, contemporary ethical frameworks have evolved to support the inclusion of people with dementia as research participants.

In research settings, ethics committees have strict protocols to ensure respectful, inclusive, and safeguarded participation of PLWD, acknowledging their right to contribute knowledge about their own experiences. In contrast, self-advocacy—particularly as supported and promoted by dementia charities—remains unregulated by ethical oversight. Although the inclusion of people with Lived Experience (LE) is increasingly sought in grant applications and co-design, involvement is often symbolic and extractive, and PLWD are frequently expected to share deeply personal, painful narratives without remuneration or meaningful influence.

Finally, this paper argues that the absence of ethical protocols for dementia self-advocacy—despite their necessity in research—represents a serious oversight with implications for exploitation, exclusion, and rights violations, risking inclusion being extractive and performative. It calls for the urgent development of independent, transparent, and rights-based ethical guidelines that extend beyond research institutions to any organisation involving PLWD in advisory, advocacy, or representational roles. These independent ethical guidelines are needed to govern advocacy involvement, ensuring that the principles of dignity, autonomy, and informed participation extend beyond the boundaries of academic research and into all spheres where people with dementia are invited to contribute.

**Biography**

Kate is an author, speaker, a PhD Candidate and independent researcher at the University of South Australia, School of Justice and Society, investigating disability rights for people with dementia, including access to rehabilitation for people with dementia and older people receiving community, respite or residential care. Kate is an award-winning disability rights and global campaigner, including the 2017 Australian Of The Year in South Australia. She has been a major catalyst for rehabilitation for people with dementia, and for dementia to be managed as a disability. She has a MSc (Dementia Care), BPsych, BA, is a retired chef and retired nurse. She is an Ambassador for Step Up For Dementia Research Australia and the Australia Day Council SA. Her other research has focused on dementia rehabilitation, and reparations and redress for harm to people in residential care.

## Community-minded research

12:25 – 12:40

*"Do we need ethics for that?" A provocation from a project to grow James Lind Alliance Priority Setting Partnerships in Australia*

**Dr Bec Jenkinson**
The University of Queensland

**Abstract**

Participatory research priority setting increases the relevance of health and medical research and reduces research waste. The James Lind Alliance (JLA) is a UK not-for-profit organisation that brings consumers and clinicians together in Priority Setting Partnerships (PSPs) that identify and prioritise unanswered questions on specific health topics to guide researchers and funders. Each JLA PSP yields a 'top ten' list of priorities, which have become increasingly important in decision-making processes by health and medical researchers and funders in the UK.

This presentation aims to provoke discussion about the ethical dimensions of participatory research priority setting for health and medical research in Australia, and will argue that JLA PSPs, while ethically significant, should not require human research ethics review.

The JLA approach offers a transparent, inclusive, and ethically robust framework for engagement, that aligns with ethical principles but should not be considered research. There is variability in the way HRECs handle JLA PSPs, both within Australia and compared to international practice. Treating JLA PSPs as research requiring ethical review creates barriers to the authentic use of this participatory approach, particularly in terms of time and associated resources. Where PSPs are recognised as 'pre-research' engagement activities they are exempted from ethical review. This presentation will invite HREC members and researchers to consider how HRECs can support, rather than constrain, participatory research priority setting.

**Biography**

Bec is a health consumer-turned-researcher, with more than 15 years experience in health consumer advocacy and representation. Bec completed her PhD at UQ in 2018, but then wrestled with what exactly it means to be a consumer-researcher. Increasingly though, she thinks she was just ahead of her time! Bec now leads a program of research as part of UQ's Clinical Trials Capability (ULTRA) to strengthen consumer and community involvement in clinical trials. As part of this, she is partnering with the UK's James Lind Alliance to address barriers to participatory research priority setting in Australia.

## Community-minded research

12:40 – 13:00

*Involving people with disability as consumer research partners*

**Associate Professor Margaret Wallen**
Australian Catholic University

**Abstract**

CP-Achieve is a research group which focuses on optimising health and wellbeing outcomes of young people with cerebral palsy. A core value of this NHMRC-funded Centre of Research Excellence was to embed consumer involvement in all research activities, with involvement spanning each stage of the research cycle. Four advisory groups were formed comprising respectively – adolescents, young adults, parents, and a truly unique initiative, users of augmentative and alternative communication (AAC). AAC users are people whose main form of communication is not speech. Also, individual CRP joined research teams as researchers or consultants and contributed to projects from inception to translation. Over 40 CRP were part of CP-Achieve.

People with cerebral palsy have a physical disability, which may be mild to profound, and many have co-existing communication, hearing, vision, and intellectual disability, mental health issues and medical fragility. Researchers and CRP together developed an extensive repertoire of knowledge and resources to ensure that each individual's involvement was tailored for their

unique accessibility needs. The resources also aimed to optimise involvement of people with cerebral palsy in their roles as CRP and ensure they felt that their participation was psychologically safe.

The purpose of this presentation is to demonstrate how substantial and authentic consumer involvement was achieved in CP-Achieve and discuss the principles adopted. The presentation will also share practices the team would approach differently in the future and provide access to publicly available translation resources developed in collaboration with CRP. The aim in sharing these resources is to build skills and confidence in researchers and HRECs about how people with disability are involved as partners in research.

**Biography**
Margaret is Associate Professor in Occupational Therapy at Australian Catholic University and a chief investigator with CP-Achieve, a NHMRC-funded program of research focussing on the health, wellbeing and participation of young adults with cerebral palsy. Margaret's dual passions are optimising outcomes for people with cerebral palsy through research, and championing consumer involvement in research from idea generation through to implementation of findings to inform policy and practice. Margaret led the consumer involvement theme with CP-Achieve and will be presenting experiences and resources which were developed to support researchers to involve people with cerebral palsy and other disability to be involved as consumer research partners.

## 13:15– 14:15 Abstract parallel session 1

13:15 – 13:30
*Advancing health equity in randomised controlled trials: a collaborative implementation science approach*
**Mark Liu**
The University of Queensland

**Abstract**
Randomised controlled trials (RCTs) are the foundation of evidence-based healthcare. Unfortunately, their findings often lack generalisability due to underrepresentation of diverse population groups (e.g. non-English speaking or non-metropolitan communities), which can greatly limit future implementation and scalability. Targeted research funding exists for underserved populations, however, the majority of mainstream RCTs rarely incorporate health equity-focused design or reporting. This project seeks to embed health equity into the RCT lifecycle through collaborative, interdisciplinary efforts.

The project will commence with a Queensland-based think tank involving diverse stakeholders across the investigator-led RCT sector, e.g., academic researchers, ethics and governance professionals, and consumer and community representatives. The think tank is expected to generate actionable strategies and foster a state-wide community of practice focused on health equity in RCTs. The cross-sectional study will identify key barriers and enablers within the RCT sector, while the consensus activity will produce standardised reporting guidance for demographic data.

This initiative represents an important initial step toward transforming the RCT landscape in Australia. By embedding equity considerations into RCT design, conduct, and reporting, the project aims to ensure that future health innovations are ethically sound and scalable for Australia's diverse population. Through interdisciplinary collaboration and co-design, this project will build the groundwork for a national research agenda that will raise the standard for health equity in clinical trials.

**Biography**
Mark is an implementation science research fellow with ULTRA, The University of Queensland Clinical Trials Capability team. Previously, he was an exercise physiology clinician researcher who focused on individuals living with advanced cancer and disability, and has led multi-site and multi-state (NSW and VIC) stepped-wedge hybrid trials that included regional hospitals.

## Abstract parallel session 1

13:30 – 13:45
*The role of familial carers in palliative care for terminal cancer: the ethics of autoethnography*
**Associate Professor Susan Hemer**
University of Adelaide

**Abstract**
This paper analyses the experience and ethics of the practice of the autoethnography Susan conducted as a carer for her husband. In recent years autoethnographic accounts of health conditions have become more common, but remain somewhat debated both in terms of their focus and the ethical issues that they raise. In the health field, autoethnography allows access to experiential accounts of illness, caring and death that are not easily accessible via other methodologies. In contrast to autobiography which has greater focus on an individual's experiences and emotions, an autoethnography has greater emphasis on socio-cultural analysis.

Autoethnography is an accepted method in the social sciences that combines self-narrative with critical socio-cultural and historical analysis (Chang 2008). This is implied in the words *auto* = self; *ethno* = culture/society, and *graphy* = writing (Ellis & Bouchner 2000: 740). Autoethnographic accounts vary in the weighting that they give to each of these parts. Chang (2016) strongly emphasises that in the field of health there is much greater value in emphasising the sociocultural and historical context of experiences, rather than just the emotional. Chang characterises this as analytic versus evocative autoethnography.

However, the deep intimacy of an autoethnographic account raises ethical questions about ongoing informed consent, confidentiality, and the positioning of the author. How should an autoethnographer decide what should be recorded or shared? Whose story is it, and who owns the data? This paper will raise these issues through an account of Susan's own experience with autoethnography.

**Biography**
Susan is a medical anthropologist with more than 2 decades of qualitative research experience both in Australian and overseas. Her work explores emotions, grief and death, communicable and non-communicable illnesses, and ethical issues related to cross-cultural and ethnographic research. She joined the University of Adelaide's ethics committees in 2021 and currently serves on the HREC for the University. Her most recent research is an autoethnographic exploration of the work of caring for a family member with terminal cancer.

## Abstract parallel session 1

13:45 – 14:00
*Consent-to-continue in intensive care clinical trials: a mixed-methods scoping review and recommendation for reporting [unrecorded session]*
**Renate Le Marsney**
The University of Queensland

**Abstract**
In acute clinical scenarios, consent-to-continue (CTC) permits patient enrolment into clinical trials, and commencement of intervention, prior to obtaining consent. Consent, for continuation in the trial, is then sought once the emergent situation has passed. Despite implementation of CTC in intensive care unit (ICU) research, there are few studies investigating implementation and acceptability of this approach. The objective was to describe implementation, experiences, and determinants of acceptability of CTC for neonatal, paediatric and adult ICU clinical trials.

A mixed-methods scoping review was conducted. Academic databases, and databases of ICU trials, were used to identify studies that reported the results of randomised controlled trials (RCTs) and/or the views and acceptability of CTC in ICU clinical trials.

5,454 ICU RCTs were screened. 159 RCTs used CTC (2.9% of all ICU RCTs; 13/1,144 [1.1%] neonatal RCTs, 13/567 [2.3%] paediatric RCTs, 133/3,743 [3.6%] adult RCTs). CTC was used either alone (26/159; 16.4%) or in combination with another consent approach, predominantly prospective consent (128/159; 80.5%). 158/159 (99.4%) of studies were led from high-income

settings and most (81.1%) were published in the past 10 years. Only 39 RCTs reported consent rates separately by method of consent.

Despite many jurisdictions allowing CTC and high acceptability to patients, families, and substitute decision makers, it is still uncommon in ICU trials. Inconsistent reporting, socio-cultural differences between countries undertaking ICU RCTs, variation in ethics committee approval, and lack of educational materials to support CTC processes may be impediments to uptake. These results will inform the development of future processes, educational and implementation materials and reporting standards to enhance understanding, implementation and reporting of CTC.

**Biography**
Renate is the Data Manager for the Children's Intensive Care Research Program (ChIRP) at The University of Queensland. She has a background in study coordination and data management in the areas of oncology, neonatology, and paediatric intensive care research. She has a strong interest in utilisation and development of technical solutions for the effective management and monitoring of clinical trial data, as well as research in the area of clinical trial methodology.

## Abstract parallel session 1

14:00 – 14:15
*Enabling decentralised clinical trials in NSW and ACT*
**Anna Hartley**
Cancer Institute NSW

**Abstract**
Decentralised Clinical Trials (DCTs) can reduce the burden of clinical trials for rural, regional and remote communities by having specific activities occur away from a central research facility. DCTs have the potential to reach more diverse participant populations, ensure equitable access to clinical trials, improve participants' experience, and ensure research data is more representative of the patients intended to benefit from the clinical interventions.

There are multiple approaches to decentralising clinical trials, from a simple arrangement for follow up appointments to occur by virtual care, through to fully decentralising all activities so that the participant never has to attend the main research site. There are also multiple ways to implement a DCT approach.

In order to build a statewide framework for the conduct of DCTs, the Decentralised Clinical Trials Framework Project has conducted an extensive review of the current state of DCTs in NSW and ACT and uncovered a high-level of DCT usage, variation in how these approaches are implemented, and uncovered key enablers to help organisations use more DCT approaches.

An environmental scan was conducted including 83 stakeholder meetings, and semi-structured interviews with 41 individuals. Stakeholders represented public health staff from 11 health districts and across 18 different roles related to clinical trials.

The results of the review will be presented and discussed in terms of the key enablers that focus on community, equity, and governance.

**Biography**
Anna is the Project Lead for the Decentralised Clinical Trials Project which is a partnership between Cancer Institute NSW and the Rural Regional and Remote Clinical Trials Enabling Program (RRR-CTEP). The project aims to develop a statewide framework for the conduct of decentralised clinical trials across NSW and ACT, leveraging the skills and expertise of the clinical trial workforce in regional, rural and remote areas. Anna has a long history of project management for health services, with clinical experience as an Allied Health clinician in NSW and Victoria.

## 13:15 – 14:15 Abstract parallel session 2

13:15 – 13:30
*Inclusivity in informed consent*
**Natalie Day**
Parenting Research Centre

**Abstract**
The Parenting Today™ National Survey aims to capture the voices of parents and carers across Australia to find out what raising children is like today. Leveraging the success of the Parenting Today in Victoria surveys conducted every 3 years since 2015, the Parenting Research Centre has taken the survey to scale to better inform policy and service provision for families across the nation. In a quest for a truly representative dataset, the Parenting Research Centre consulted with peak bodies, community organisations, and those working alongside parents to design an accessible survey, ensuring that consent from diverse parent sub-groups was informed; thus, upholding the basic ethical principal of autonomy.

This presentation discusses the specific methods undertaken in the Parenting Today National Survey to bring inclusivity to processes of obtaining consent based on the capacity for autonomy through accessible and varied channels to access participant information. This inclusivity encompasses another key tenet of ethics; that research should not be carried out to the benefit of only certain population groups (National Health and Medical Research Council, 2023).

The analysis will also provide insight into the most commonly accessed consent formats, shedding light on the future of best practice toward inclusive informed consent practices. The session will discuss the challenges of recruiting at-risk populations, incentivising (or not) online survey participation, and present tried and tested solutions to these issues in order to realise the intent of a far-reaching and inclusive national survey.

**Biography**
Natalie is Acting Senior Research Specialist with the Parenting Research Centre (PRC). She is a passionate and detail-oriented researcher with demonstrated experience of project design and implementation. She brings extensive expertise in designing, implementing and evaluating research projects with a focus on child development, parent-mediated interventions, and education outcomes for children. She has experience in leading mixed-methods research, RCTs, delivering program evaluations for external stakeholders, and managing all aspects of project delivery including ethics approvals, participant engagement, data collection, analysis, and reporting. She has produced high-impact publications, translated findings to accessible formats for diverse audiences, and collaborated across multidisciplinary and international teams including the ARC Centre of Excellence for the Digital Child and The Lego Foundation. In her current role at the PRC, Natalie has contributed to the design and execution of a large scale, national project including project coordination, research design, stakeholder engagement, data analysis, and report-writing and knowledge translation.

## Abstract parallel session 2

13:30 – 13:45
*Simplifying consent: a user-centred approach for people with schizophrenia*
**Gabrielle Ritchie**
The University of Queensland

**Abstract**
Background: Individuals with schizophrenia face unique cognitive challenges, including difficulties with attention and memory which can hinder their ability to fully understand and engage in traditional, typically paper-based patient information and consent forms (PICFs). These often lengthy, jargon-heavy documents can act as barriers rather than facilitators of informed consent, potentially limiting an individual's participation in research and excluding a marginalised population from studies that could benefit them. This study aimed to redesign a traditional, paper-based PICF to improve accessibility, comprehension, and engagement in clinical trials for individuals with schizophrenia while maintaining ethical and regulatory integrity.

The co-design process resulted in a two-tiered PICF system: (1) a short, user-friendly

version featuring icons, a question-and-answer format, and simplified language to facilitate initial discussions, and (2) a detailed, text-based version maintaining essential study details while incorporating consistent visual elements for ease of navigation. Additional design enhancements included increased white space, thoughtful use of colour, and a focus on autonomy-supportive language.

By involving individuals with lived experience, the project developed a PICF format that is more accessible, inclusive and empowering. These redesigned forms have been integrated into ongoing research and approved for use in a national multi-site clinical trial. This work underscores the importance of tailoring consent materials to diverse populations and provides a framework for improving consent processes across research involving individuals with cognitive or communicative challenges.

**Biography**

Gabrielle is a clinical psychologist, an Adjunct Research Fellow at the UQ School of Medicine, and a Senior Allied Health Clinician at Queensland Health. She is interested in improving the physical and mental health outcomes of people with severe mental illness. Her current work focuses on co-designing lifestyle interventions to improve the lives of individuals with schizophrenia as well as the use of behaviour change techniques to assist with self-management strategies for people with severe mental illness.

## Abstract parallel session 2

13:45 – 14:00

*Consent and command: ethical dilemmas of studying the military*

**Ofelia Carreno**
University of Adelaide

**Abstract**

This presentation focuses on a less frequently discussed area: human research involving current and former Defence personnel. In this context, the recent Royal Commission into Defence and Veteran Suicide has underscored the importance of improving data use and establishing a dedicated research translation function in Defence. However, little attention has been paid to the processes and challenges surrounding HRECs within military settings.

At the heart of this presentation is a core ethical dilemma: can members of the Australian Defence Force (ADF) truly give informed and voluntary consent to participate in research? The presentation is structured to assist researchers and HREC members unfamiliar with military institutions in navigating processes and making ethical assessments. The discussion on aligning military research ethics with broader national standards may also be of interest to policymakers.

It begins with a narrative review of relevant academic and grey literature. Next, using the lens of ‘soldiers as subjects’, which recognises that Defence personnel are under a chain of command and within a culture of obedience, the presentation explores historical controversies in informed consent, such as the immunisation of quinoline anti-malarial drugs to ADF personnel in the late 1990s and early 2000s, and the recent DVA MATES scandal. These case studies elucidate how past failures have shaped best practice.

Although best practice in health and medical research increasingly emphasises participant engagement throughout the research lifecycle, particularly under Chapter 4 of the *National Statement,* such approaches remain underdeveloped in military research contexts. The talk will argue that we should adopt a proactive approach to ethical preparedness. Even modest steps, such as involving personnel in research priority-setting or policy co-design, would mark meaningful progress.

**Biography**

Ofelia is a Law and Economics (Advanced) undergraduate student at the University of Adelaide and a research assistant engaged in legal scholarship at Adelaide Law School and UNSW Canberra. She also works as a Research Project and Policy Officer at SA Pathology. Ofelia’s

key interests include health and medical research policy, international humanitarian law, legal history, and the intersection of law, ethics, and technology.

## Abstract parallel session 2

14:00 – 14:15

*Increasing CALD recruitment in cancer clinical trials by engaging interpreters and clinical trial staff*

**Dr Suzanne Grant**
Western Sydney University

**Abstract**

People from culturally and linguistically diverse (CALD) backgrounds face significant barriers to participating in cancer clinical trials. Ensuring that CALD individuals have access to clinical trials is vital for scientific representativeness and upholding human rights, particularly the right to health. The Cancer Institute NSW and Western Sydney University, in collaboration with community representatives sought to improve participation through 2 initiatives i) developing workforce capacity of the Health Care Interpreting Services (HCIS), and ii) building Clinical Trial Unit (CTU) staff capacity to work effectively with interpreters. This presentation hopes to provide education to the HRECs based on these research findings, about why consideration of CALD participation is important when reviewing clinical trial applications.

**Biography**

Suzanne is a Senior Research Fellow at NICM Health Research Institute. Her research focuses on the use and effectiveness of mind-body and biologically based therapies in both cancer and integrative healthcare. She has been in the research field for over 30 years, first in market research, government, and for the last 10 years in complementary and integrative medicine health care research. Her research aims to support individuals with cancer to live their best life during treatment and after. Her research includes the role of mushrooms, micronutrients, acupuncture, oncology massage, yoga, mindfulness and other therapies in people with cancer. Suzanne completed her PhD at Western Sydney University investigating the use of Chinese Herbal Medicine in the treatment of pre-diabetes (or impaired glucose tolerance) and insulin resistance. She is also registered as a Chinese Medicine Practitioner with close to 20 years experience.

## 14:14 – 15:15 HREC chair debate

Topics for debate:

- Reduction vs centralisation of HRECs
- Waivers, consent and publicly available data
- Ethics committees are facilitators of researchers / using consumer engagement as a prompt for part of this discussion?
- Providing feedback to researchers, do HRECs need peer review?
- Can we trust AI in ethics review?

**Panellists**

**Professor Michael Martin**
see page 15

**Associate Professor Mandy Downing**

Mandy is identified through maternal lineage to the Ngarluma and Yindjibarndi people of the Lerrumugudu (Roebourne) area. However, as the granddaughter of a Stolen Generation survivor, she was raised off-Country on Wadjuk Noongar Boodjar. Mandy is the Dean of Indigenous Futures, responsible for ensuring Australia's Indigenous futures across the nation's culture and economy are supported and considered in the learning, research, and partnership activities of the Faculty of Humanities at Curtin University.

Mandy is an applied scientist in Indigenous Australian research with research interests in institutional racism and the first Aboriginal person appointed as a Dean in the Faculty of Humanities at Curtin University. Nationally, Mandy is the Senior Indigenous Facilitator for the National Environmental Science Program Sustainable Communities and Waste Research Hub and is the Co-Chair of the Australian Institute of Aboriginal and Torres Strait Islander Studies National Research Ethics Committee.

In the community, Mandy co-designed an emerging leadership program through the Western Australian Aboriginal Leadership Institute for Aboriginal and Torres Strait Islander youth and has voluntarily facilitated this since its inception in 2019. She is a 2023 inductee into the Western Australian Women's Hall of Fame for her contributions to education for more than 20 years. Most recently, Mandy is a co-editor of the newly published book The Routledge Handbook of Human Research Ethics and Integrity in Australia.

**Associate Professor Suzie Ferrie**

Suzie is the senior critical care dietitian at Sydney's Royal Prince Alfred Hospital and clinical Associate Professor at the University of Sydney. Her PhD focused on nutritional assessment and monitoring of critically ill patients, and her honours degree in philosophy focused on ethics and zombies. Ongoing research interests include gut function in critical illness, and nutritional requirements in the ICU population. After 10 years as a member of the hospital's HREC, she took on the role of Chair earlier this year.

**Professor Andrew Crowden**

Andrew is a bioethicist and philosopher with extensive experience in clinical, research and organisational ethics. Andrew has Master of Bioethics and PhD degrees from the Monash Bioethics Centre. He is Honorary Professor in Philosophy at the University of Queensland's School of Historical and Philosophical Inquiry where he is Chairperson of the University of Queensland Ethics Advisory Group (UQEAG). Andrew is an Honorary Professorial Fellow at the University of Melbourne and an Adjunct Professor at the University of the Sunshine Coast (UniSC). He is Chair of WEHI (Walter and Eliza Hall Institute of Medical Research) HREC, Chairperson of UniSC HREC, Executive member of the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Research Ethics Committee, Stream Leader for Research and Innovation for the Australasian Association of Bioethics and Health Law (AABHL), a member of CSIRO's Australian Health Biobank (AHB) Advisory Group, a member of the Australasian Association of Philosophy (AAP) Philosophy in the Community Committee (PiCC) and is Director and Lead Consultant at Crowden Consultants.

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